MedSun Newsletter #50, July 2010

Articles

What Happens to an Adverse Event Report Submitted to FDA?

Print Item
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CDRH Transparency website

Please see the Adverse Event Flowchart to see what happens when adverse event reports are submitted to the FDA through the MedWatch Adverse Event Reporting program. This information is posted on the CDRH Transparency website, which provides additional information to help the public understand information about regulatory decisions and the rationales for those decisions, descriptions of regulatory processes, and data to support CDRH actions and public health activities.

Additional Information:

Adverse Event Flowchart. CDRH Transparency Website. June 2010. http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHTransparency/UCM212516.pdf[7]

CDRH Transparency Website. About the Center for Devices and Radiological Health. June 2010. http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHTransparency/default.htm[8]

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Infusion Pump Improvement Initiative: Public Workshop presentations are available

Print Item
E–mail Item

FDA News and Events (Medical Devices) Website

FDA recently launched the Infusion Pump Improvement Initiative to address persistent safety problems associated with infusion pumps. As part of this initiative, a public workshop was held on May 25-26, 2010 to discuss infusion pump problems and possible future actions. Presentation slides and transcripts are now available online. To view the slides and transcripts, please see the link below.

Additional Information:

News and Events (Medical Devices). Public Meeting: Infusion Pump Workshop, May 25-26, 2010. Workshop presentations online available:

http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm203299.htm[10]

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Class I Recall and Safety Investigation of Counterfeit Polypropylene Surgical Mesh - Update

Print Item
E–mail Item

FDA MedWatch Safety Alert

This is an update of FDA's Initial Communication on counterfeit polypropylene surgical mesh, which was issued on March 11, 2010. It contains additional information about the recall and updates FDA's recommendations and activities.

Additional Information:

FDA MedWatch Safety Alert. Class I Recall and Safety Investigation of Counterfeit Polypropylene Surgical Mesh. June 10, 2010.
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm[12]

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Defibtech DBP-2800 Battery Packs used in Lifeline AED and ReviveR AED - Recall

Print Item
E–mail Item

FDA MedWatch Safety Alert

Defibtech, LLC, notified customers of a recall of certain DBP-2800 Battery Packs used in the Lifeline AED and ReviveR AED. When the AED is used with an affected battery pack, the AED may falsely detect an error condition during charging for a shock, then cancel charge and not provide therapy.

Additional Information:

FDA MedWatch Safety Alert. Defibtech DBP-2800 Battery Packs used in Lifeline AED and ReviveR AED – Recall. June 14, 2010.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm214916.htm[14]

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Chondrolysis Linked to Intra-articular Infusions

Print Item
E–mail Item

By Joan Ferlo Todd, MS, BSN, RN FDA
FDA Medical Device Safety

The FDA has received approximately 35 reports of chondrolysis in patients who received

continuous intra-articular infusions of local anesthetics with elastomeric infusion devices for postoperative pain management. In general, elastomeric infusion devices are safe when used properly. However, these devices haven't been approved by the FDA for intra-articular administration.

Additional Information:

FDA Medical Device Safety. Chondrolysis Linked to Intra-articular Infusions. June 2010. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm214699.htm[16]

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Tubing Misconnections: Making the Connection to Patient Safety

Print Item
E–mail Item

Pennsylvania Patient Safety Advisory

One of the main reasons for tubing misconnections is that many types of tubing for different types of medical devices incorporate Luer connectors. These connectors contribute to misconnections because they allow functionally dissimilar tubes or catheters to be connected together. Between January 2008 and September 2009, 36 events of tubing misconnections were reported to the Pennsylvania Patient Safety Authority involving various types of misconnections. Methods for reducing the likelihood of tubing misconnections include equipment design solutions and administrative policies and work practices.

Additional Information:

Pennsylvania Patient Safety Advisory. Tubing Misconnections: Making the Connection to Patient Safety. June 2010. http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Jun7(2)/Pages/41.aspx[18]

FDA Medical Device Safety. Luer Misconnections. May 12, 2009. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm134863.htm[19]

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Safeguarding the Storage of Drug Products

Print Item
E–mail Item

Pennsylvania Patient Safety Advisory

A well-organized drug-storage system can reduce the risk of medication errors. However, events reported to the Pennsylvania Patient Safety Authority describe how breakdowns in the storage of medications have contributed to drug product mix-ups. Analysis reveals

that nearly 73% of the events reached the patient. The most frequently reported event type was wrong drug. This article discusses strategies to address these problems.

Additional Information:

Safeguarding the Storage of Drug Products. Pennsylvania Patient Safety Advisory. June 2010.
http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Jun7(2)/Pages/46.aspx[21]

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OR Fire Prevention Video Available

Print Item
E–mail Item

Pennsylvania Patient Safety Advisory

The Anesthesia Patient Safety Foundation offers this free video on OR Fire Prevention, on its website. The video promotes best practices regarding the prevention of fires in the operating room (OR), including controlling oxygen concentration levels at or near the surgical site, and extrapolates OR fire statistics based in part on analysis of events reported to the Pennsylvania Patient Safety Authority. The Pennsylvania Patient Safety Advisory also has several articles discussing OR fire prevention, including "Airway Fires during Surgery", which is accompanied by an educational poster that highlights ways to minimize and fight airway fires.

Additional Information:

OR Fire Prevention Video Available. Pennsylvania Patient Safety Advisory. June 2010.
http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Jun7(2)/Pages/60.aspx[23]

Anesthesia Patient Safety Foundation. Prevention and Management of Operating Room Fires. February 2010.
http://www.apsf.org/resource_center/fire-safety.mspx[24]

FDA MedSun Newsletter. Practice Advisory for the Prevention & Management of Operating Room Fires. February 2009. Online Available:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=33#6[25]

FDA MedSun Newsletter. Fire Safety and Oxygen: A Patient Guide. January 2009. Online Available:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=32#7[26]

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LabNet

FDA/CDRH Public Meeting: Oversight of Laboratory Developed Tests

Print Item
E–mail Item

FDA News and Events (Medical Devices) Website

FDA will hold a public meeting July 19-20, 2010 to obtain input on implementing a reasonable, risk-based, and effective regulatory framework for laboratory-developed tests (LDTs), in vitro diagnostics that are manufactured by and offered in the same laboratory. FDA will collect and review all comments and information presented at the public meeting and adopt a regulatory approach that will provide the public with safe and effective tests. For more information about the workshop, please see the link below.

Additional Information:

FDA/CDRH Public Meeting: Oversight of Laboratory Developed Tests (LDTs), Date July 19-20, 2010. News & Events (Medical Devices).
http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm[28]

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The Path to Personalized Medicine

Print Item
E–mail Item

The New England Journal of Medicine

The success of personalized medicine depends on having accurate diagnostic tests that identify patients who can benefit from targeted therapies. Increasingly, however, the use of therapeutic innovations for a specific patient is contingent on or guided by the results from a diagnostic test that has not been independently reviewed for accuracy and reliability by the FDA. The agency's goal is an efficient review process that produces diagnostic–therapeutic approaches that clinicians can rely on and allows companies that invest in establishing the validity and usefulness of tests to make specific, FDA-backed claims about benefits.

Additional Information:

The New England Journal of Medicine. The Path to Personalized Medicine. June 15, 2010.
http://content.nejm.org/cgi/content/full/NEJMp1006304[30]

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HeartNet

Heart Failure Associated with Pacemaker-Induced Dyssynchrony

Print Item
E–mail Item

The Journal of Nurse Practitioners/American College of Nurses

Recent research has shown that permanent right ventricular (RV) pacing is causally linked to heart failure (HF). Permanent RV pacing is thought to cause inter- and intraventricular dyssynchrony, which leads to a decreased systolic contraction and a decreased ejection fraction. Primary care nurse practitioners should be cognizant of the signs and symptoms of HF in this patient population to diagnose and treat HF as a result of pacemaker-induced dyssynchrony.

Additional Information:

The Journal of Nurse Practitioners/American College of Nurses. Heart Failure Associated with Pacemaker-Induced Dyssynchrony. May 2010.
http://www.npjournal.org/article/S1555-4155(10)00072-3/abstract[32]

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Featured HeartNet Report of Interest

Print Item
E–mail Item

HeartNet has received a report on a patient with a Medtronic Secura ICD. This problem is related to the May 2010 physician letter from Medtronic regarding a rare device software issue in some ICD and CRT-D devices. A software update will be available to correct this issue. The reported event states:

The patient was admitted via ED three days ago, with the chief complaint: "defibrillator keeps going off." The patient was in rapid atrial fibrillation at that time, "which necessitated multiple ICD charges and shocks in rapid succession. The charge time exceeded the allowance of the device and the end of service indicator was triggered: recommendation is to perform an ICD generator change/replacement since the ICD will not function properly." The ICD was explanted and another ICD implanted. The device was returned to Medtronic for evaluation. The patient's outcome from the EP perspective was satisfactory.

Please review the physician letter and correction from Medtronic below.

Additional Information:

MedSun Report. May 7, 2010. Online Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/medsun_details.cfm?ID=%25%22%5DS%3F%27%2FP%20%0A&CFID=46931419&CFTOKEN=29c536eb70892af6-33CD3[34]

Medtronic. Important: Medical Device Correction – Consulta CRT-D, Secura DR/VR, Concerto II CRT-D, Virtuoso II DR/VR, Maximo II CRT-D, Maximo II DR/VR. http://www.medtronic.com/icd-crtd-correction/[35]

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HomeNet

Medical Device Home Use Initiative: Public Workshop presentations and transcripts now available

Print Item
E–mail Item

FDA News and Events (Medical Devices) Website

FDA recently launched the Medical Device Home Use Initiative to improve the safe use of medical devices in the home environment. As part of this initiative, a public workshop was held on May 24th, 2010 to address the implications surrounding the safe and effective use of medical device technology migrating into the home. Presentation slides and transcripts are now available online and address topics such as, premarket review process, postmarket surveillance, risks in the home environment, user characteristics, training issues and wireless technologies. To view the presentation slides and transcript notes, please see the link below.

Additional Information:

Medical Device Use in the Home Environment Workshop: Implications for the Safe and Effective Use of Medical Device Technology Migrating Into the Home, May 24, 2010. News and Events (Medical Devices). Workshop presentations online available: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm205804.htm[37]

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KidNet

Human Factors Can Cause Pediatric Medical Device Adverse Events

Print Item
E–mail Item

American Academy of Pediatrics (AAP) News

KidNet, the pediatric subnetwork of the Medical Surveillance Network (MedSun), had received reports of medical device adverse events involving cracked luer hubs of peripherally inserted central venous catheters. The adverse events initially were attributed to users over-tightening catheter connectors. Follow-up by the Food and Drug Administration (FDA) with the manufacturer resulted in design and material improvements to the luer hub, which resists cracking.

Additional Information:

American Academy of Pediatrics (AAP) News. Human Factors Can Cause Pediatric Medical Device Adverse Events. February 2010.
http://aapnews.aappublications.org/cgi/content/full/31/2/14-a?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=human+factors&searchid=1&FIRSTINDEX=0&resource[39]

2009 Medical Safety Calendar on FDA Luer Misconnections Website.
http://www.fda.gov/cdrh/luer/[40]

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Highlighted MedSun Reports

Highlighted Reports

Print Item
E–mail Item

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period April 1 through April 30 2010. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

ANESTHESIOLOGY

Device:

Type: Adult Ventilator
Manufacturer: Drager Medical
Brand: Evita Xl
Model#: 8414900

Problem:

The ventilator stopped working while on a patient. The source of the problem was a bad power supply. Further investigation revealed that since 01/2004, 10 power supply units (PSU) have been replaced for a similar problem. This represents 21% of inventory. We have documented 2 types of failures. One occurs on the AC side. There is a component failure on the board; the AC power fails and the backup batteries do not engage. This results in a catastrophic failure. The other occurs on the DC side. The charging relay for the internal battery fails. When the device is taken off AC power (for transport), neither the internal nor external batteries engage.

==========
Health Professional's Impression
==========
poorly designed power supplies

==========
Manufacturer response for Adult Ventilator, Evita XL
==========
In 2007, a PSU was returned to the vendor for evaluation. The results of the investigation are unknown at this time.

Device:
Type: Ventilator, High Frequency Oscillatory
Manufacturer: Carefusion 207
Brand: Sensormedics
Model#: 3100 B

Problem:
Teenage patient status post (S/P) respiratory arrest with history of Downs syndrome and self injurious behaviors intubated on admission to the pediatric intensive care unit (PICU). Patient with significant pulmonary edema, reactive airway and subcutaneous emphysema. Patient placed on 3100B Carefusion SensorMedics oscillating ventilator which malfunctioned. Patient was ambu bagged for 75 minutes while troubleshooting by respiratory. Patient required Dopamine for hypotension. Upon inspection of circuit, noted to have broken luer fitting which provides connection to the end of the circuit for measuring mean airway pressure had broken (white airway pressure port). This is the second occurrence of this type.

==========
Health Professional's Impression
==========
Broken luer port.

See device image:

CARDIOVASCULAR

Device:

Type: Defibrillator, External
Manufacturer: Philips Medical Systems
Brand: HeartStart MRX
Model#: 3535A

Problem:
With manipulation of catheters in the dilated and atrialized right atrium, the patient had a two minute episode of wide-complex tachycardia, tolerated poorly from a hemodynamic perspective. He failed to cardiovert with a dose of Adenosine and synchronized DC (direct current) cardioversion was requested. During charging of the defibrillator set for 7 joules, the nurse changed the selected energy to 4 joules and unsynchronized discharge was delivered. The nurse called out the settings prior to the shock and the staff visualized that the defibrillator was in sync mode. After delivery of 4J of unsynchronized energy, the patient went into ventricular fibrillation. He received 30 seconds of CPR and was defibrillated with 10J unsynchronized successfully to sinus rhythm on first attempt. His hemodynamic status immediately stabilized. This defibrillator was removed from service and another defibrillator was brought in. The cardiac cath procedure continued. During this time, the second defibrillator was noted to be going in and out of synchronization. This was identified as strips were being recorded and printed during the case. The question is whether this is due to a technical (machine) error or another outside energy source, i.e. cell phone interference.

Manufacturer response (as per reporter) for 2 Defibrillators, Philips HeartStart MRx

Plan to come to hospital to evaluate both defibrillators.
Comment from FDA: This report was received through MedSun in March 2010. MedSun has since received similar reports with this product.
Device:

Type: Catheter, Cardiovascular, Balloon Type
Manufacturer: Edwards Lifesciences

Brand: Swan Ganz Cco Vip
Model#: 139HF75P

Problem:
Possible defective thermistor. Swan-Ganz catheter inserted in preparation for open heart surgery. In the cardiovascular intensive care unit (CVICU) it was noted that the temperature reading indicated a temp of 105 degrees F. Nurse tried recalibrating machines (GE monitor), patient repositioned. This did not change the readout. There was no known difficulty in inserting the device and it worked while in the OR.

==========
Health Professional's Impression
==========
Possible defective thermistor on catheter.

==========
Manufacturer response for Continuous cardiac output monitoring device, Swan Ganz CCO
==========
They will be picking up the catheter this week for inspection.

Device:

Type: Clamp, Vascular, Reprocessed
Manufacturer: Ascent Healthcare Solutions
Brand: Femostop
Lot #: 879762 & 878439

Problem:
Patient was post heart cath procedure and in ICU for arterial line/femoral sheath removal. The RN pulled the femoral sheath with a FemoStop. The bulb inflated but would not hold pressure. The FemoStop was from lot #879762. Staff got another FemoStop with a lot #878439 which also failed. Finally a FemoStop with a different lot number was used and worked appropriately. The RN reported that another ICU unit had also had a similar experience with a FemoStop with the lot #879762. The patient experienced minor bleeding. All product was pulled from the shelves and is being held by Materials Management.

==========
Health Professional's Impression
==========
The bulb would not stay inflated so would not provide the compression-assist for vascular closure.

==========

Manufacturer response
==========
Materials Management has collected the malfunctioning devices and said that they were notifying the manufacturer. Manufacturer is coming to the facility to look into the events.

Device:
Type: Injector And Syringe
Manufacturer: Medrad, Inc.
Brand: Stellant Dual Syringe Kit/quick Fill Tube
Lot #: 99775 and 99776
Cat #: SDS-CTP-QFT

Problem:
Multiple problems with tubing not adhering to connectors and T-connectors cracking. For example, in one case the connector will separate from the tubing. In another case the connector hub is cracking when used. This has happened multiple times recently, but 4 times within 24 hours where the product has been saved. We have retained 6 defective sets from two lot numbers. MedRad says they are aware of the problem and will provide replacement tubing. MedRad declined to tell me what lot numbers were affected.
This is not a new product for the facility. In most cases this occurred while setting up the injection. No harm to patients, but technicians are concerned that a fragment of the connector could fall into the contrast. In one case they were not sure so they discarded the contrast and started over.
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Health Professional's Impression
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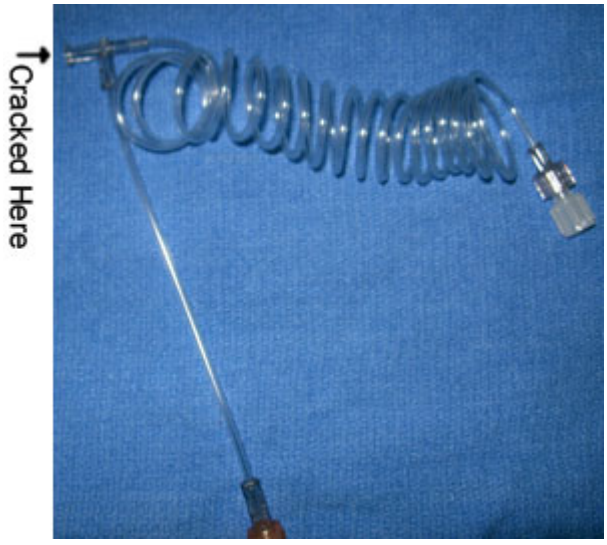
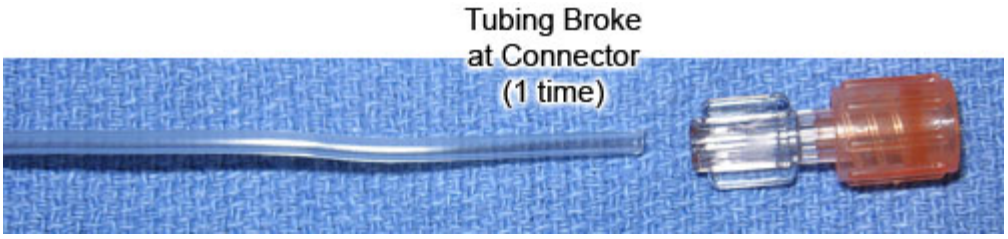
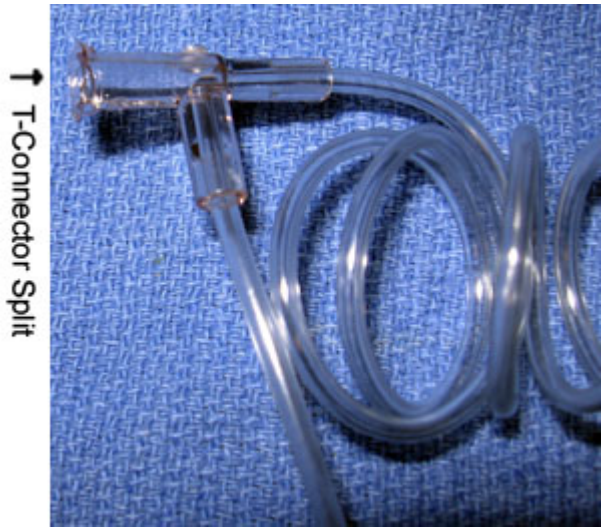
Defective product.

See device images:







Device:

Type: Oxygenator, Membrane, Silicone
Manufacturer: Medtronic Perfusion Systems
Brand: Ecmo 1500
Model#: 1500

Problem:
Over the course of the last 3 weeks, five 1.5 m2 Medtronic silicone ECMO membranes were found to have leaks. Two occurred while on patients, and three occurred on stand-by circuits.

If the leak is bad enough, the patient has to be separated from ECMO support to change the membrane, thus putting the patient at risk. The ECMO manager met with the manufacturer who said he would analyze the defective membranes which he then took with him. He thought Medtronic would be doing their own FDA reporting. We did trace the lot numbers and found them all to be of the same lot. There were no more of that lot in-house and we were given a supply from a different lot.

Device:

Type: Prosthesis, Vascular Graft, Of 6Mm And Greater Diameter
Manufacturer: Gore

Brand: Propaten
Lot #: 3139866PPO26
Cat #: H470045A

Problem:
Graft is designed to prevent clots; patient had this arterial venous (AV) fistula graft inserted by surgeon. Heparin solution was utilized. Vendor representative present during procedure (surgeon's initial experience with graft). Within hours it clotted and patient had to return emergently to the OR and undergo general anesthesia and have another procedure performed to remove Gore Graft. Patient was fine after the second procedure.

==========
Health Professional's Impression
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Graft claims it is designed not to clot. This graft clotted almost immediately after surgery requiring emergency return to surgery. Revision of AV graft, thrombectomy, creation of radial cephalic fistula and removal of graft, left arm.

==========
Manufacturer response for AV Fistula Vascular graft, Gore
==========
Vendor first response was to pick up graft. I informed him a report was being filed. He is calling the company to discuss how the vendor desires the graft to be returned and to which department.

Device:

Type: Syringe, Prefilled, Contrast Injection
Manufacturer: Covidien
Brand: Optiray 320 Ioversol Injection 68% Syringe, Ultraject
Lot #: V033B
Cat #: 132381

Problem:
CT Technologist loaded a pre-filled contrast media syringe into the faceplate/housing of a Mallinckrodt-Covidien Optivantage ceiling mounted bedside contrast media injector and initiated injector procedure. The syringe "exploded" while delivering contrast media.

It is unknown at this time whether the event was caused by a failure of the pressure sensing device in the arm of the injector, a mis-loaded syringe or a failure of the syringe due to a manufacturing defect. The device is designed to deliver at 4.0 cc's/sec up to a psi limit of 300.

No issues were identified with the Optivantage Injector. However, user error was offered by the vendor due to damage found on the piston knob, indicating that the syringe was

not aligned properly with the ram prior to injection.

Given that two additional events have occurred, the manufacturer has subsequently requested all of the syringe information. We are also considering requesting a new injector device.

Comment from FDA: MedSun has received similar reports about exploding syringes.

DENTAL

Device:

Type: Dental Handpiece
Manufacturer: StarDental
Brand: Star
Model#: 430K SW

Problem:
During a dental restoration procedure a small burn was sustained to the patient's skin just below the lower left lip line from the dental handpiece.

==========
Health Professional's Impression
==========
The burn is a complete match (size and shape)to the back side of the handpiece that touched the patient at the location of the burn.

GASTROENTEROLOGY & UROLOGY

Device:

Type: Catheter, Foley
Manufacturer: Bard Medical Products
Model#: 165816
Cat #: 165816

Problem:
Foley catheter had been inserted during hospital visit. Patient returned to urologist's office to have foley catheter removed. (Staff unable to recall which patient). Nurse recalls that physician drew back on syringe while draining balloon. This is contrary to recommendations from manufacturer. The physician attributed the problem to defect in product. Vendor recommends additional in-service on proper techniques.

Device:

Type: Tube, Feeding, System,
Manufacturer: CORPAK Medsystems
Brand: Cortrak Enteral Access System WCortrak Transmitting Stylet
Lot #: 40282
Cat #: 20-9431TRAK
Other #: REORDER # 20-9431TRAK

Problem:
A Corflo feeding tube malfunctioned when it was connected to a Cortrak Enteral Access System machine. The green dot started in the middle, on the right of the screen instead of the top center. A waveform pattern was very irregular upon advancing the feeding tube. An attempt was made to restart the insertion procedure and to restart the Cortrak machine; but there was no improvment in the situation. The effort was abandoned with this specific feeding tube. A new feeding tube was obtained. It was then connected to the same machine and there were no issues. The staff does not know how the incident occurred.

GENERAL & PLASTIC SURGERY

Device:

Type: Grasper, Atraumatic
Manufacturer: Richard Wolf Medical Instruments Corporation
Brand: Wave Side
Model#: 8394.292
Other #: 8394.2922 (complete instrument set)

Problem:
Surgical Technician reports while patient undergoing laparoscopic Gastric Bypass procedure the grasper being used by the Physician's Assistant (PA) began leaking a "reddish weakened fluid" out of the handle/hinge. The grasper was immediately removed from the field. Fluid continued leaking from handle/hinge. PA has been using this device for approximately 6 years and has never had this occur before. Two cultures of fluid taken, one from instrument and one from drape where liquid dripped onto. Both were sent to lab. Infection Control, Sterile Processing and OR staff involved all met to determine possible causes. It is felt the fluid most likely came from the patient and could possibly have "back flowed" up the shaft of the grasper due to pressure from insufflation of patient's abdomen. Sterile Processing verified device had been used on previous case two days prior and was in the decontaminator at 19:47 on that day, it went to assembly at 7:21 am on the next day and was placed in sterilizer at 11:03 am. Per procedure, the device was taken apart from the decontaminator, sat for nearly 12 hours, then placed on white towel where Sterile Processing personnel use pipe cleaners, alcohol and blow out the device with airhose, then put it back together and place it into a tray. Sterile Processing personnel believe had this been from a previous case it would have been dry and flaky.

Question whether there may be a crack in assembly somewhere or possibly gasket? Sterile Processing states device is serviced every 25 uses by our contracted instrument repair service. This device has not been modified. The procedure was finished with no further issues and the patient was sent to PACU for recovery.

Device:

Type: Pack, Total Hip
Manufacturer: PHS
Lot #: 958215
Cat #: 139910

Problem:
When total hip pack was opened, foreign object was visualized on corner position on another wrapped pack inside.

GENERAL HOSPITAL

Device:

Type: Bariatric Bed
Manufacturer: Kinetic Concepts Inc (KCI) USA, Inc.
Brand: Kci Barimaxx Ii Bed
Model#: 60035

Problem:
The bed involved was the BariMaxx 2 Model #60035. Code Blue called for patient in BariMaxx 2 bed. Anesthesiologist arrived and attempted to move bed away from wall to get into position to intubate but was unable to move bed; had to intubate from patient's side (bad angle). Wheel locks were disengaged but the bed remained immovable. Nursing supervisor and staff unable to locate a master switch to control bed. Bed had no power during part of resuscitation. After code, nurse supervisor and 3 nurses reviewed bed - found power switch at base of the head of bed in an area not visible with a patient in the bed or with the head of bed not elevated.

Owner's manual was available but instructions not clear or easy to find regarding use in an emergency. Potential for great risk if emergency evacuation ever needed.

After these events were reported, the transport supervisor went to examine bed - reported they were able to get the bed out of the room but it was very difficult to move and required 2 people to push.

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Health Professional's Impression

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Bed did not move;

Staff have reported concerns regarding the KCI "power drive system" as this is not intuitive and difficult to work with in an emergency.

==========
Manufacturer response for bariatric bed, KCI BariMaxx 2 bed
==========
The KCI field rep was advised of our concerns. We have not received any official response at this time.

Device:

Type: Computer Controlled Medication Dispensing System
Manufacturer: Carefusion
Brand: Pyxis 3500
Model#: 3500

Problem:
An anesthesiologist in our open heart surgery room reported that the medication removed from a drawer in the Pyxis 3500 felt "warmer" than normal.

Vendor has examined the machine and there have been two conference calls made to the vendor by pharmacy staff - one revealing the problem to Carefusion and the second to discuss mitigation issues to resolve the problem.

Temperature measurements were conducted at 3 points of the machine: drawer 2.1, drawer 2.2 and an external point on the rear of the machine. Ambient room temperature was measured as well, at varying times during the day for 3 days. Temperatures (in degrees Fahrenheit) measured in the drawers ran from 4 degrees above ambient (room) to 13.5 degrees above ambient. In all cases, drawer 2.1 was 1 degree higher than drawer 2.2. Ambient temperature (room) ranged between 66.4 to 69 degrees at time of measurements.

Vendor has stated that temperature inside unit should stay within 9 degrees of ambient, but we believe this value was derived without anything in the drawers. Temperatures in our Open Heart room can range from 66 - 78 degrees. Based on that information, a 9 degree window on top of this takes several drugs outside the manufacturer's recommended temperature range for drug stability.

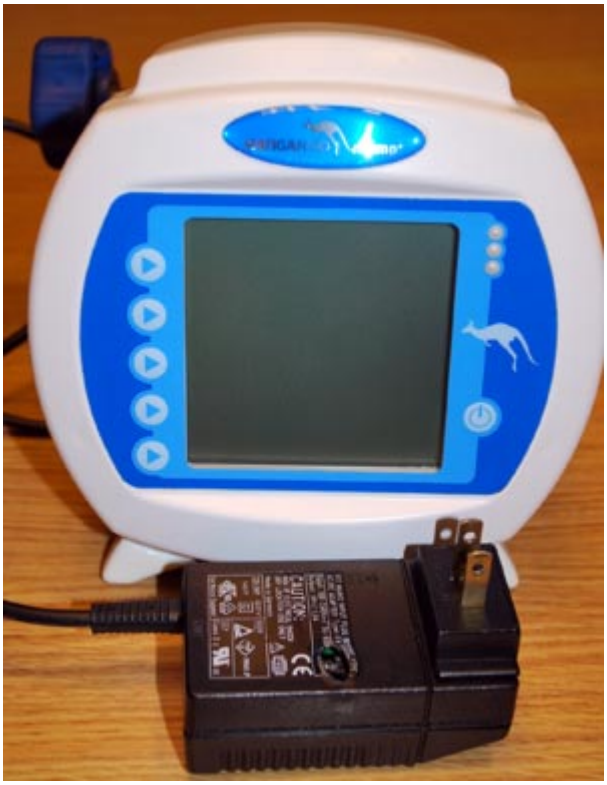
Device:

Type: Enteral Feeding Pump
Manufacturer: Kendall

Brand: Kangaroo Epump
Model#: 382400

Problem:
Power cord plug containing electronics and transformer failed and burnt a hole in the case of the power plug. Fire department called and responded and patient was evacuated from their room.

See device images:



Device:

Type: Fall Monitor And Bed Sensor
Manufacturer: J.T. Posey Company
Brand: Posey Keepsafe
Model#: KeepSafe Deluxe
Cat #: 8374 (Fall Monitor)
Other #: 8307 (Over Mattress Bed Sensor (incl RJ-11 cable and connector)

Problem:
Patient in bed placed on top of Keep Safe Posey brand bed-alarm pad. Posey bed alarm sounded frequently during the night. Nurse entered room and reset alarm each time, checked connections, and bed pad placement. Morning care provided and nurse left room. Immediately notified that patient was on the floor. Bed alarm did not sound.
The batteries were verified as having been in proper range although I can state without hesitation that they did not contribute to this failure in any manner. This device failed because the wires that are connected to the pad were so frayed that they were hanging on by a thread. The pads are connected to the monitor via RJ-11 connectors and four associated wires (the same as you would see on a standard telephone cord). Each wire has ~8-10 twisted strands. When we received the pad in Clinical Engineering it was evident that the strands were completely severed on one of the 4 wires. The other three wires were in very poor condition – having been pulled out of the RJ-11 connector so you could see the exposed color wire sheathing of the remaining three wires. These cords are the least durable component in this system and highly vulnerable to failing – which is quite

likely why the manufacturer affixes a permanent label to the pads stating that these devices are not warranted beyond 6 months of use.

==========
Health Professional's Impression
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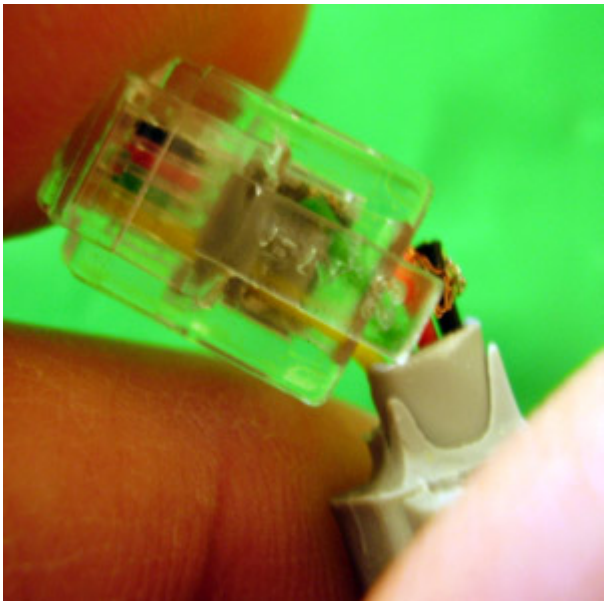
The device failed to alarm when the patient attempted to get out of bed.

See device images:



Device:

Type: Infant Incubator
Manufacturer: Drager Medical
Brand: Caleo
Model#: Caleo

Other #: ARYK-0027,ARYK-0028,ARYK-0030,ARWF-0032,ARWF-0033,ARXB-0015,ARXB-0014

Problem:
The canopy is becoming cracked, especially around the hole in the top. The hospital believes the cracks appear to be heat stress fractures. The hospital has been using CaviCide as the cleaning/disinfectant agent for the last 3 to 4 months instead of Kleenaspetic (made by Draeger), which is recommended for use with the Caleo incubator. Draeger has discontinued making Kleenaspetic and it is no longer available for purchase. The sales rep believes we are using an "unapproved" cleaner. These fractures do not appear to be that type of fracture and the cleaner being used is an industry standard cleaner.

Device:

Type: Infusion Pump
Manufacturer: CareFusion
Brand: Alaris Point Of Care Unit, Model 8000
Model#: 8000
Lot #: N/A
Cat #: 8000

Problem:
The nurse was entering a bolus dose of Versed in mg/Kg and recognized that the Alaris Model 8000 pump control unit calculated the total dose delivery value in mg incorrectly. Patient weight was 3.6 Kg and dose was .28 mg/Kg. Total dose should have been 1.01 but the pump displayed 1.23 mg. Total volume appeared to be calculated correctly. Further investigation showed that the total dose display was incorrect, but the actual volume delivered was correct and accurate. Problem determined to be with Model 8000 only (model 8015 does not exhibit the problem), with weight based drugs in which the units for continuous delivery and the units for bolus delivery are different in the Guardrail drug library definition. In this case continuous was defined as mcg/Kg/min and bolus delivers was in mg/Kg. CareFusion was notified and has duplicated the problem.

==========
Health Professional's Impression
==========
Unknown problem with how the Guardrail software calculates and/or displays the total bolus dose value when used on a Model 8000 PCU. Model 8015s appear to function normally and cannot be demonstrated to exhibit the failure mode. Calculation errors seem to be clustered around a weight of 3.57 Kg and a bolus dose of 0.284 mg/Kg. A more extensive test of Versed resulted in 97 failure points.

==========
Manufacturer response for Infusion Pump, Alaris Point of Care Unit, Model 8000

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I have been getting regular updates about the progress of their investigation and we have shared technical data at every phase of the investigation. Very professional and responsive in all regards. Very good communication and follow-up.

Device:

Type: Iv Pump And Tubing
Manufacturer: Hospira
Brand: Symbiq Iv Infusion Pump
Model#: 1602604
Lot #: 85171 5H Hospira tubing

Problem:
Patient is receiving weekly chemotherapy and premedication treatment for diagnosed vulvar cancer. Patient given pre-medication consisting of Zofran and Decadron IV on total volume per Pharmacy of 79 mls to infuse over 15 minutes at 316 ml/hr. Symbiq pump programmed accordingly to pharmacy parameters on premedication bag. At approximately 1040 RN talked with patient, noting that medication was delivered down to air in bag and chamber and the pump was still pumping the air closer to patient, not yet having detected it and pump did not give "air in line" alarm. RN closed white roller clamp to stop medication/air in tubing where it was at. Pump was alerting occlusion (D/T roller clamp activated). Pump reading volume to be infused was still at 4.08 mls. Pump turned off after tubing removed. Tubing saved and marked at 54 inches past chamber that loads into Hospira Symbiq, full of air. Pump and tubing were sent to Biomedical department and have been sequestered. Bio-Technician has been unable to duplicate the "air in line" problem. Patient received infusion of Cisplatin 80 mg via another Symbiq pump with 500 ml Dextrose 5% 1/2 normal Saline with 10 meqKCl, 1 gm Magnesium sulfate & 25 gm Mannitol infused over 60 minutes. No complications or adverse effects from the infusion. No air reached the patient.

==========
Health Professional's Impression
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Unknown - we have been unable to duplicate the "Air in Line" through BioTech testing of the pump and the tubing. Problem could possibly be linked to the cartridge or tubing set. Bio-Technician observed a difference between the tubing sets received previously and the current tubing sets.

==========
Manufacturer response for IV pump and tubing, Symbiq IV infusion pump
==========
Hospira clinical bulletin issued April 2010 recommending avoiding the practice of over programming the volume to be infused with the intention of using the "Air in Line" alarm to alert the clinician to the end of an infusion, and recommended use of an administration

set or extension set with an air eliminating filter where clinically acceptable. Hospira is continuing to investigate these reports. Hospira representatives will be at hospital later this week to assist with investigation of event.

Device:

Type: Mattress, Flotation Therapy, Non-powered
Manufacturer: Kinetic Concepts Inc.
Brand: Rik

Problem:
Ventriculoperitoneal (VP) shunt valve was set at a certain performance level number and then the nurse verified the setting was altered. The valve is set with a kit that positions the performance level with a magnetic field. This patient was using a gel Rik mattress that has magnets on the front side to support the sheets nearby the head. The magnets are powerful enough to change the shunt setting. However, it cannot be determined with certainty if the patient's head was close enough to the magnets to make the change.

Device:

Type: Pca Pump
Manufacturer: SMITHS MEDICAL ASD, INC.
Brand: Cadd Solis
Model#: 2100

Problem:
The CADD Solis Model 2100 PCA pump was designed with an air in line sensor and alarm. Using sets from Smiths Medical, the system develops "champagne" bubbles which affix to the sensor, are difficult to extract, and trip the alarm ceasing PCA operations. The air-in-line alarm has developed into a nuisance alarm. We have scores of event reports where nursing (following proper protocol) must investigate every alarm, look for these "champagne" type bubbles removing the patient from their pain control. The manufacturer response has been to advise "turning the alarm off". Because patients would be at risk for air embolism (particularly in the pediatric population that uses this device), that response, given the fact that the device was designed to detect air (and has detected air albeit with too great a sensitivity), is irresponsible. The pumps have two settings for detecting: high/low. We have already set the pump on the lowest setting without amelioration of the problem.

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Health Professional's Impression
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The manufacturer claims that PCA pumps in the past did not have air sensors at all. While we recognize that only Europe at the moment requires air sensors in line,

nonetheless, the sensor was incorporated into the "new" pump for obvious safety reasons, and it was purchased with this safety feature in mind. The risk to patients by continuing with the faulty sensor/system is interrupted pain management. The risk of following the manufacturer's advice to "turn the alarm off" is undetected air in line leading to air embolism. Either way, the patient is at risk of harm which is untenable.

==========
Manufacturer response for PCA Pump, CADD Solis Model 2100
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The manufacturer has stated that 70% of hospitals using this device have "turned off" the alarm on the advice of the manufacturer.

Device:

Type: Software, Pharmacy Management
Manufacturer: Siemens Medical Solutions USA, Inc.
Brand: Siemens Pharmacy

Problem:
The Pharmacy medication alert system was updated and the alerts were inadvertently turned off. The alerts were down for approximately 7 days.

Device:

Type: Warmer, Infant Radiant
Manufacturer: Draeger Medical Systems, Inc.
Brand: Iics90
Model#: SYSTEM 7880

Problem:
At 1800 hours the infant warmer in the newborn nursery started smoking. There was not a baby in the warmer, but there were other babies in the nursery. After seeing the smoke come out of the top of the warmer it was noticed that there were also small flames popping out of the upper vent holes. The warmer was unplugged. The flames and smoking stopped. The warmer was pushed out into the hall where it was then sent to BioMed for repair.

NEUROLOGY

Device:

Type: Shunt, Central Nervous System And Components
Manufacturer: Medtronic Neurosurgery

Brand: Strata Shunt Valve
Model#: 42855
Lot #: A11195

Problem:
Ventriculoperitoneal (VP) shunt valve was set at a certain performance level number and then the nurse verified the setting was altered. The valve is set with a kit that positions the performance level with a magnetic field. This patient was using a gel Rik mattress that has magnets on the front side to support the sheets nearby the head. The magnets are powerful enough to change the shunt setting. However, it cannot be determined with certainty if the patient's head was close enough to the magnets to make the change.

Device:

Type: Shunt, Central Nervous System And Components
Manufacturer: Integra LifeSciences Corporation
Brand: Hermetic Lumbar Catheter Closed Tip
Model#: INS-5010
Lot #: 1092990
Cat #: REF-INS-5010
Other #: Date on package 2012-06

Problem:
Doctor's. note stated: Procedure for endovascular repair of thoracic aneurysm. Surgeon requests placement of lumbar drain for monitoring cerebral spinal fluid pressure. Elected to attempt placement at the L2-3 interspace with a right paramedian approach. The Tuohy needle was advanced into the thecal sac with good cerebrospinal fluid (CSF) flow. The catheter was placed with the wire to 15cm. I could not extract the wire from the catheter and I elected to remove the catheter with the wire and the needle. There was some resistance to withdrawing the catheter/wire after the needle was removed and I noted the catheter was compromised with splitting at the 5cm mark. I continued to pull the catheter carefully but it only continued to stretch and after the wire was out the catheter tore completely with some catheter remaining below the skin level. Upon examining the catheter and comparing to a new catheter apparently 2-6cm of catheter was left in the patient. It was decided to continue with the procedure and place a new catheter. A new catheter was placed at the L3-4 midline without incident and with a good flow through the catheter.

OBSTETRICS/GYNECOLOGY

Device:

Type: Hydro Thermablator System
Manufacturer: Boston Scientific Corporation

Brand: Hta Procerva Procedure Set
Lot #: 38607
Cat #: Moo6560210

Problem:
Upon filling and during pressure checks, as well as filling checks, on repetitive occasions, with the manufacturer representative for the system present, an adequate seal on the cervix could not be obtained. Multiple attempts. Too much fluid leakage and safety alarms engaged, not allowing system to heat up. Ablation procedure aborted. No harm to the patient.

OPHTHALMIC

Device:

Type: Silicone I/a Tips
Manufacturer: ALCON Research, LTD
Brand: Silicone I/a Tip

Problem:
This device comes nonsterile and is sent to Sterile Proccessing Department for processing. They are supposed to be good for 10 uses but after the first use the silicone tip splits. This can not be detected by the naked eye, it has to be examined under the microscope to see the split in the tip. This could cause damage to the eye during surgery if not detected by the surgeon. I can not provide lot #'s or packages as these are discarded when they arrive in SPD and the devices do not have lot #'s on them.

Silicone I/A tips coming with minimal silicone protection at end of tip, surgeon states not usable this way, potential for ripping eye capsule. MD requesting tips be discarded (brand new out of box.

ORTHOPEDIC

Device:

Type: Arthroscope
Manufacturer: ASCENT HEALTHCARE SOLUTIONS
Brand: Formula Agressive 6Flute
Model#: 375-940-000
Lot #: 140679
Cat #: 375-940-000

Problem:
The male patient was having left shoulder arthroscopic rotator cuff repair, subacromial

decompression, distal clavicle resection and debridement of a Type 1 superior labral tear. The physician noted the patient did have a Type 1 slap tear. His subscapularis tendon was intact. The Type 1 slap lesion was debrided using a motorized shaver. After this was accomplished, the patient was noted to have a small, full-thickness rotator cuff tear that could be observed from the undersurface. This area was marked. The subacromial space was entered. Subacromial decompression was performed using a motorized bur. Once the bur was used, it was noted that it left very tiny flakes of metal inside the patient's shoulder.

==========
Manufacturer Response for arthroscopic shaver, Ascent
==========
We received a letter dated one month ago stating the device was inspected and the inner shaft of the device was observed to be tightly lodged inside the outer shaft and was unable to be separated. Metal particulates and biological material was observed on the device indicating evidence of clinical use. The proximal end of the inner shaft hub was observed to be broken, confirming our report. The letter was received 2 days ago.

Device:

Type: Arthroscope
Manufacturer: ASCENT HEALTHCARE SOLUTIONS
Brand: Formula Resector Cutter
Lot #: 165724
Cat #: 375-562-000

Problem:
The patient was having right shoulder arthroscopic debridement, subacromial decompression, distal clavicle resection, open rotator cuff repair, and open biceps tenodesis, right shoulder. The surgeon made a 4 cm incision across the anterolateral aspect of the shoulder. Dissection was carried through the subcutaneous tissue and the anterolateral border from the acromion was opened as was the deltoid split between the anterolateral heads. The rotator cuff tear was identified. The surgeon took a bur and debrided the bone to allow good bleeding. The surgeon then used pull stitches to mobilize the rotator cuff. Once the bur was used, it was noted that it left tiny pieces of metal in the patient's shoulder.

RADIOLOGY

Device:

Type: Pacs System, Software
Manufacturer: GE Healthcare
Brand: Centricity

Model#: Centricity
Other #: client software version 2.1.5.10

Problem:
We use a GE Centricity PACS. One of the Radiology groups that reads for the hospital has asked that the filters that identify "Unread" studies be created with the logic that removes cases that are being viewed (a.k.a. "locked") from the unread list - They don't want to open the cases to see that another user is viewing the study.

Recently, studies were found to be locked that were not being displayed - As locked, there was a delay in the interpretation as the studies were not on an unread work list.

It is unknown whether the issue is caused by a bug in the software. The same version of the client was re-installed and the problem has not continued.

Device:

Type: System, Ultrasound, Pulse Volume Recorder
Manufacturer: Parks Medical Electronics
Brand: Flo Lab
Model#: 2100sx Flo Lab

Problem:
We are testing various location tracking technologies (often referred to as "RFID") for the past few months in Recovery Room and Biomed shop. The goal is to assess the feasibility of employing one or more of these technologies throughout the institution.

A technician and a clinical engineer recently discovered that one of these vendor's technologies, one that uses infrared (IR) as their primary locating technology, causes interference with a medical device that has an active IR port, namely a pulse volume recorder (PVR). We have been able to duplicate the interference with these devices and are investigating whether other medical devices with active IR ports may be affected. Thus far no other devices have been identified. (We do have other devices with IR ports - but on those identified to date the ports are not active when in clinical use).

The IR location system (vendor: Centrak) has been shut down. There have been no occurrences of interference with a device in clinical use. The discovery was made in our Biomed shop while a technician was testing the PVR machine.

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Medical Device Problem Summaries

Summary of MedSun Reports Describing Adverse Events With Print Item

External Infusion Pumps

E–mail Item

External infusion pumps are medical devices that deliver fluids, including nutrients and medications such as antibiotics, chemotherapy drugs, and pain relievers, into a patient's body in controlled amounts. [1]

This summary report will focus on devices that achieve infusion through internal cassette-based methods and will exclude products that deliver infusate through syringes.

Over the past year, MedSun has received 55 adverse event reports associated with External Infusion pumps manufactured by the following companies:

-B. Braun Medical Inc.
-Baxter International, Inc.
-Cardinal Health, Inc.
-Carefusion Corporation
-Hospira,Inc.
-Iradimed Corporation.
-Sigma International, Inc.
-Smiths Medical Inc.

The reports were submitted by 28 hospitals between June 2009 and June 2010.

The problems associated with the 55 reports mentioned above were:
-Pump onscreen error: 15
-Over infusion: 11
-Failure of pump sensor: 8
-Unexpected Shutdown: 7
-Battery-related failure: 4
-Pump Library Malfunction: 3
-Under-infusion/Non-delivery: 3
-Problem Related to Pump-User Interaction: 3
-IV Infiltration: 1

A total of 0 reports involved a patient death. The patient injuries listed below were reported in 10 of these 55 reports.
-Delay in Therapy: 15
-Overinfusion-related Illness: 5
-Underinfusion-related Illness: 3
-Swollen extremity: 1
-No Impact on Patient Noted: 31

The FDA has recently started an Infusion Pump Improvement Initiative. This agency is taking the following steps to address problems observed with the use of external infusion pumps:
1. Establish additional requirements for infusion pump manufacturers;

2. Proactively facilitate device improvements; and
3. Increase user awareness.

For more information on this initiative, please visit the following webpage: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202501.htm [2]

The following table lists the MedSun reports that are described in the device problem summary above.

Adverse Event Table

Manufacturer Name	Device Brand Name	Model	Event Description
CARDINAL HEALTH 303, INC.	SIGNATURE GOLD	N|A	A CRITICALLY ILL, UNSTABLE PATIENT ON MULTIPLE INFUSIONS WAS BEING TRANSPORTED EMERGENTLY FOR A TEST/PROCEDURE. THE DOUBLE CHAMBER INFUSION PUMP FAILED MIDWAY DURING TRANSPORT. THE NURSE DISCONNECTED A NON-CRITICAL THERAPY FROM ANOTHER WORKING PUMP THAT WAS SAFE TO INFUSE VIA GRAVITY. THEN, THE WORKING PUMP WAS REPROGRAMMED TO INFUSE THE CRITICAL THERAPY FROM THE MALFUNCTIONING PUMP UNTIL A REPLACEMENT PUMP COULD BE OBTAINED. THIS IS THE SECOND TIME THIS HAPPENED IN ONE DAY ON TWO DIFFERENT PUMPS. OUR BIOMEDICAL ENGINEERING DEPARTMENT FOUND THAT THE ALARIS INFUSION PUMP SUFFERED TWO "ENTIRE INSTRUMENT ILLEGAL RESETS." ACCORDING TO THE ALARIS TECH SUPPORT, THESE ERRORS ARE MICROPROCESSOR

			ERRORS AND THE INSTRUMENT IS IN NEED OF REPAIR. THE PUMP(S) WERE SENT TO THE MANUFACTURER FOR FURTHER ANALYSIS AND REPAIR.
BAXTER HEALTHCARE CORPORATION	COLLEAGUE 3CX	N|A	THE TRIPLE CHANNEL COLLEAGUE CX INFUSION PUMP WAS SENT TO THE BIOMEDICAL ENGINEERING DEPARTMENT BECAUSE THE NURSE NOTICED THE GUARDIAN/DRUG LIBRARY SETTINGS WERE ALTERED FROM THE STANDARD SET THAT THEY UTILIZE. OUR IN HOUSE BIOMEDICAL ENGINEERING DEPARTMENT CONFIRMED THE GUARDIAN/DRUG LIBRARY SETTINGS HAD "DEFAULTED" BACK TO THE FACTORY SETTINGS, AND OUR CUSTOMIZED SETTINGS THAT ARE SPECIFIC TO OUR HOSPITAL WERE LOST (STANDARD DRUG CONCENTRATION SETTINGS, DOSAGE LIMITS/WARNINGS, ETC). THE PUMP DID NOT NOTIFY THE USER OF THIS ALTERATION IN THE GUARDIAN/DRUG LIBRARY SETTINGS. THERE ARE SERIOUS PATIENT SAFETY IMPLICATIONS ASSOCIATED WITH THIS FAILURE INCLUDING INADVERTENT OVER OR UNDER-INFUSION, UNINTENDED BOLUSES, ETC. THIS HAS OCCURRED 2-3 OTHER TIMES IN THE PAST WITH THE COLLEAGUE CX PUMPS. DURING TESTING OF THE PUMP BY OUR IN HOUSE BIOMEDICAL ENGINEER, IT WAS NOTED IN THE DEVICE HISTORY LOG THAT ONE WEEK PRIOR TO THE

			PUMP COMING DOWN FOR THE GUARDIAN/DRUG LIBRARY ISSUE, THE PUMP WAS RESET DUE TO A DEPLETED BATTERY ALARM. THE NEXT DAY (DAY AFTER THE DEPLETED BATTERY ALARM), THERE WAS AN 812.02 FAILURE CODE NOTED ON CHANNEL A OF THE DEVICE, WHICH HAD RENDERED CHANNEL A INOPERABLE. THE NURSES CONTINUED TO USE CHANNEL B AND CHANNEL C.
HOSPIRA,INC.	SYMBIQ	N|A	A PUMP WAS IN USE ON A PATIENT. A SQUEAL SOUND WAS HEARD AND PUMP WAS FOUND OFF, AND NO OTHER ALARM HAD BEEN GENERATED. THE ALARM LOGS NOTED A SOFTWARE ERROR WITH MULTIPLE LINES OF OTHER INFORMATION. THE PUMP WAS SENT TO THE MANUFACTURER PER THEIR REQUEST.
HOSPIRA,INC.	SYMBIQ	N|A	WHEN ASSESSING HOURLY VITALS, THE PUMP WAS NOTED TO HAVE A WHITE SCREEN WITH ERROR MESSAGE 15 DISPLAYED AND WAS NOT INFUSING. WE ARE UNSURE OF HOW LONG THE MEDICATION HAD NOT BEEN INFUSING. THERE WAS NO ALARM GENERATED TO NOTIFY THE CLINICIAN OF THE ERROR. THIS WAS CONCERNING BECAUSE PATIENT HAD JUST HAD A STENT INSERTED AND WAS ON A MEDICATION TO KEEP THE STENT PATENT AT TIME THE PUMP WAS FOUND TO BE NONFUNCTIONAL. OUR BIOMEDICAL ENGINEERING DEPARTMENT VERIFIED S308 ERRORS IN THE

			LOG FILE. WE RETURNED THE PUMP TO THE MANUFACTURER FOR REPAIR.
CARDINAL HEALTH 303, INC.	ALARIS SYSTEM MODULE	8100	THE FIRST INCIDENT INVOLVED A PEDIATRIC PATIENT WHO WAS BEING TRANSPORTED TO THE OR (OPERATING ROOM) ON A VENTILATOR WITH AN ALARIS PUMP ON AN IV POLE. THE ALARIS IV PUMP SPONTANEOUSLY SHUT OFF STATING "CHANNELS DISCONNECTED" DURING TRANSPORT MULTIPLE TIMES REQUIRING NURSE TO MANUALLY RESTART ALL CHANNELS. THE PATIENT WAS NOT HARMED BY EVENT. THE SECOND INCIDENT OCCURRED WITH AN ADULT ICU (INTENSIVE CARE UNIT) PATIENT. DURING TRANSPORT, THE ALARIS PUMP WAS BUMPED SLIGHTLY BY THE TRANSPORTER WHICH RESULTED IN THE PUMP SHUTTING DOWN. A REQUIRED MANUAL RE-SET WAS DONE.
CARDINAL HEALTH 303, INC.	ALARIS SYSTEM MODULE	8100	A NURSE PROGRAMMED THE INFUSION PUMP TO ADMINISTER INSULIN AT 100UNITS/HOUR, BUT SHOULD HAVE PROGRAMMED THE PUMP TO INFUSE AT 10UNITS/HOUR. THE PUMP PERMITTED THIS INFUSION RATE, BUT SHOULD HAVE PREVENTED ANY RATE OVER 70UNITS/HOUR. APPARENTLY THE PUMP REVERTED TO "ANESTHESIA THERAPY" WHICH ALLOWED THIS RATE OF INFUSION. IT IS UNKNOWN HOW THE PUMP REVERTED TO ANESTHESIA

			THERAPY, AS THE NURSE WOULD NOT HAVE BEEN ABLE TO PROGRAM THIS. PLEASE NOTE THAT THIS SETTING IS NOT TO BE CONFUSED WITH "ANESTHESIA MODE," WHICH WAS NOT SELECTED. ROUTINE BLOOD GLUCOSE MONITORING SHOWED SIGNIFICANT DECREASE IN BLOOD GLUCOSE LEVELS. THE PATIENT RECEIVED DEXTROSE PER HOSPITAL PROTOCOL TO RAISE BLOOD SUGAR TO WITHIN NORMAL LIMITS. THE PATIENT WAS NOT PERMANENTLY HARMED FROM THIS EVENT. THE MANUFACTURER IS PERFORMING AN EVENT LOG INVESTIGATION FOR BOTH THE PUMP MODULE INVOLVED AND THE CPU, WHICH IS NOT YET COMPLETED.
CARDINAL HEALTH 303, INC.	ALARIS SYSTEM PC UNIT	8015	EPTIFIBATIDE DRIP WAS INFUSING AT 12ML/HR. A NEW BOTTLE WAS HUNG, AND THE RATE WAS VERIFIED FOR 12ML/HR. THE TUBING WAS PRIMED WITH APPROXIMATELY 20-30 ML OF MEDICATION TO REMOVE ALL OF THE AIR IN THE LINE, AND THE MEDICATION WAS RESTARTED. APPROXIMATELY 2 HOURS LATER, THE ALARIS PUMP STARTED ALARMING AIR IN LINE. UPON EXAMINING THE BOTTLE, IT WAS NOTED THAT THE BOTTLE WAS EMPTY. THE PUMP WAS RECHECKED TO VERIFY THE RATE OF INFUSION ONCE AGAIN. THE RATE OF INFUSION WAS CORRECT. IT

			WAS A 100 ML BOTTLE, SO 70-80 ML INFUSED OVER 2 HOURS.
BAXTER HEALTHCARE CORPORATION	COLLEAGUE 3CX	N|A	THE INFUSION PUMP WAS PLUGGED IN TO CHARGE PRIOR TO PATIENT TRANSPORT. THE PATIENT WAS TRANSPORTED FOR A CT SCAN, AND THE TRIPLE CHANNEL PUMP, WHICH WAS INFUSING VASOPRESSORS TO HELP STABILIZE THE PATIENT'S BLOOD PRESSURE, FAILED ON THE WAY BACK TO THE ICU. THE INFUSION PUMP HAD BEEN UNPLUGGED FOR APPROXIMATELY 30 MINUTES. IT ALARMED "LOW BATTERY," AND BEEPED FOR THE FIRST TIME. ONE MINUTE AFTER THE LOW BATTERY ALARM, THE PUMP FAILED. THIS FAILURE CAUSED THE ORGAN DONOR PATIENT TO CODE. THE PATIENT WAS ALREADY "CLINICALLY DEAD," BUT THE INFUSION PUMP THERAPIES WERE BEING UTILIZED TO STABILIZE THE PATIENT UNTIL THE ORGANS COULD BE HARVESTED FOR OTHER TRANSPLANTS.
HOSPIRA,INC.	PLUM INFUSION PUMP	PLUM XL AND PLUM XL3	TO UPDATE THE DRUG LIBRARY ON OUR HOSPIRA INFUSION PUMPS USING MEDNET 5.1 SOFTWARE VERSION, A NEW DRUG LIBRARY IS SENT TO THE PUMP OVER THE WIRELESS INFRASTRUCTURE IN THE HOSPITAL. AFTER THE PUMPS RECEIVE THE NEW DRUG LIBRARY, IT IS SUPPOSED TO PROMPT THE USER THAT THE NEW DRUG LIBRARY IS AVAILABLE WHEN THE UNIT IS TURNED OFF. USERS WILL OFTEN TURN ON AND THEN TURN OFF A DEVICE TO

			INITIATE THE PROMPT WHEN A DEVICE IS NOT IN USE. IT HAS BEEN FOUND THAT SOMETIMES THE PUMPS DO NOT PROMPT WHEN A NEW DRUG LIBRARY IS AVAILABLE. AN OPERATOR MAY ASSUME THAT THE INFUSION PUMP HAS THE LATEST VERSION OF THE DRUG LIBRARY BECAUSE THE PUMP DOES NOT PROMPT THAT A NEW VERSION IS AVAILABLE. DRUG LIBRARY CHANGES MAY HAVE DIFFERENT DRUG LIMITS AND/OR DRUG CONCENTRATIONS.
CARDINAL HEALTH 303, INC.	SIGNATURE GOLD	7230	CYCLOSPORINE WAS HUNG AT RATE OF 4.2 ML/HOUR TO INFUSE OVER 24 HOURS. HOWEVER, THE MEDICATION WAS COMPLETED 13 HOURS AFTER BEING HUNG. OUR IN HOUSE BIOMED TESTING OF THE PUMP REVEALED THAT THE PUMP OVER DELIVERS BY 10% AT THE 4.2ML RATE OVER 24 HOURS. THIS IS OUTSIDE OF THE MANUFACTURER'S SPECIFICATIONS, BUT DOES NOT ACCOUNT FOR ALL OF THE MISSING FLUID IF THE BOTTLE CONTAINED THE FULL 100ML TO START. THE PUMP HAS BEEN SENT TO THE MANUFACTURER FOR FURTHER ANALYSIS.
BAXTER HEALTHCARE CORPORATION	BAXTER COLLEAGUE 3CX	N|A	A TRIPLE CHANNEL COLLEAGUE INFUSION PUMP WAS BEING UTILIZED TO ADMINISTER MEDICATIONS AND IV FLUIDS. THE PUMP ALARMED, AND THE DISPLAY SCREEN ON THE INFUSION

			PUMP SAID TO RESET, BUT THE PUMP WOULD NOT RESET. IT APPEARED TO BE FROZEN. ALL THREE CHANNELS WERE INOPERABLE, AND ANOTHER PUMP HAD TO BE UTILIZED TO CONTINUE THE THERAPIES. THE PUMP WAS SENT TO BAXTER FOR REPAIR. THERE WERE NO ADVERSE PATIENT OUTCOMES.
HOSPIRA,INC.	SYMBIQ	N|A	THE INFUSION PUMP WAS PROGRAMMED FOR AN INSULIN INFUSION ON CHANNEL B OF THE DEVICE, AND PLACED IN A STANDBY MODE. WHEN THE CLINICIAN ATTEMPTED TO START THE INFUSION, THE PUMP MALFUNCTIONED WITH ERROR CODE S421, SUBGROUP 9, PUMP BOLUS OVERSHOOT. THE MALFUNCTION CAUSED A DELAY IN CARE TO A CRITICAL CARDIAC POST-OPERATIVE PATIENT. THE ALARM HISTORY AND EVENT LOGS WERE REVIEWED BY OUR BIOMEDICAL DEPARTMENT. UPON POWERING THE DEVICE BACK ON, THE CASSETTE WAS REMOVED FROM CHANNEL B OF THE INFUSION PUMP. HOWEVER, CHANNEL B WOULD NOT CLOSE AND COULD NOT BE RESET. THE PUMP WAS SENT TO THE MANUFACTURER FOR ANALYSIS. PRIOR TO THE RECENT RECALLS, WE HAD REPORTED SEVERAL SIMILAR PROBLEMS WITH ERROR CODES S321 AND S421 WHICH CAUSED DELAYS AND INTERRUPTIONS IN THERAPIES. HOWEVER, OUR

			PUMP INVENTORY WAS SWAPPED OUT AND NEW SOFTWARE WAS DOWNLOADED TO CORRECT THE ISSUES WE WERE PREVIOUSLY REPORTING. TO OUR KNOWLEDGE, THIS IS THE FIRST FAILURE OF THIS KIND SINCE OUR PUMPS WERE UPGRADED BY HOSPIRA POST-RECALL.
CARE FUSION, INC.	ALARIS SYSTEM	8100	A CRITICAL PICU PATIENT WAS ON CONTINUOUS VASOPRESSORS VIA AN INFUSION PUMP, INCLUDING EPINEPHRINE AND NOREPINEPHRINE. WITHOUT INTERVENTION, THE CHANNEL THAT WAS INFUSING THE NOREPINEPHRINE DRIP SPONTANEOUSLY BEEPED AND TURNED ITSELF OFF READING "CHANNEL DISCONNECT." THE DRIP WAS MOVED TO ANOTHER CHANNEL. LATER, DURING TRANSPORT TO CT SCAN, TWO CHANNELS (NOREPINEPHRINE AND MIDAZOLAM DRIPS) ALSO STOPPED. THE PATIENT'S BLOOD PRESSURE DIPPED SLIGHTLY, BUT RECOVERED QUICKLY WHEN THE CHANNELS WERE RESTARTED.
CARE FUSION, INC.	ALARIS SYSTEM 8100	8100	A PATIENT WAS TO RECEIVE 10 ML OF CALCIUM CHLORIDE TO INFUSE OVER 15 MINUTES. WHILE PROGRAMMING THE CHANNEL, THE PROJECTED RUN TIME DISPLAYED 30 MINUTES. THE CLINICIAN DECIDED NOT TO OVERRIDE THE PROGRAMMED TIME, AND IT WAS LEFT AT 30 MINUTES. THE SYRINGE WAS PLACED ON TOP OF THE CHANNEL USING THE VENTED SYRINGE ADAPTER.

			ONCE THE CHANNEL WAS PROGRAMMED, THE RN STARTED THE MEDICATION, AND THE RESOURCE NURSE CONFIRMED SETTINGS. THE CHANNEL MALFUNCTIONED, AND THE MEDICATION WAS INFUSED IN 7 MINUTES. THE RN DID NOT KNOW THE CHANNEL WAS MALFUNCTIONING UNTIL IT GAVE INFUSION COMPLETED IN LESS TIME THAN ANTICIPATED. THE PATIENT WAS ASSESSED AND THE PHARMACY WAS NOTIFIED, SO RN COULD CHECK FOR INSTRUCTIONS ON HOW TO PROCEED. THE PHARMACY INFORMED THE RN THAT THE INFUSION RATE WAS OK. THE PATIENT WAS MONITORED. THERE WAS NO PATIENT HARM.
IRADIMED CORPORATION	MRIDIUM 3860	3860	IRADIMED IV PUMP GAVE A "CRITICAL ERROR 1002" CAUSING THE PUMP TO SHUT DOWN. THE AMOUNT OF INFUSION TO THAT POINT WAS CORRECT. THE PATIENT DID NOT RECEIVE THE INFUSION FOR APPROXIMATELY 5 MINUTES, BUT DID NOT AWAKEN. THE INFUSION WAS RESTARTED ON ANOTHER PUMP.
HOSPIRA,INC.	PLUM A+	PLUM A+	PLUM SET IV TUBING WAS PLACED IN THE INFUSION PUMP, BUT THE PUMP DID NOT WORK. THE IV TUBING WAS REMOVED TO EXCHANGE THE PUMP FOR A NEW ONE. THE IV TUBING CASSETTE DID NOT CLOSE OFF AS OCCURS WHEN TUBING IS REMOVED FROM PUMP. THE PATIENT RECEIVED A MEDICATION BOLUS

			RESULTING IN HYPOTENSION AND BRADYCARDIA.
SIGMA INTL.	SPECTRUM	N|A	IV TUBING WAS INADVERTENTLY LOADED BACKWARDS IN THE INFUSION PUMP WHICH COULD HAVE RESULTED IN MEDICATION NOT BEING ADMINISTERED AND PATIENT'S BLOOD BEING DRAWN BACK INTO THE IV LINE. BECAUSE OF COMPLEX CONVERSION PROCESS AT OUR FACILITY TO THE NEW INFUSION PUMPS, WE REQUESTED MANUFACTURER TO WAIT UNTIL THE INSTALL WAS COMPLETED BEFORE DISCUSSING THIS ISSUE WITH US. THE MANUFACTURER RESPONDED WITH ADDITIONAL TRAINING WHEN THE MISLOADED TUBING WAS DISCOVERED. WE FEEL THAT THE DESIGN OF PUMP CHANNEL AND/OR IV TUBING LOADING PROCESS ALLOWS A CLINICIAN TO EASILY MISLOAD IV TUBING IF THE CLAMP SLIDES TOO FAR DOWN THE TUBING (AWAY FROM THE FIRST ACCESS PORT). THE LOOP CAUSED BY THIS POSITIONING OF THE CLAMP (WHICH IS ALSO THE KEY TO OPEN THE PUMP DOOR) MADE IT DIFFICULT TO DETERMINE WHICH TUBE WAS THE DISTAL END OF THE TUBE. WE ATTEMPTED VARIOUS WAYS TO MISLOAD THE TUBING IN A WAY THAT WILL "TRICK" THE PUMP INTO WORKING, AND FOUND TWO WAYS TO DO THIS EASILY. THE PUMP DESIGN

			RELIES ON ITS LABELING AS WELL AS THE NURSE REMEMBERING TO TRACE THE IV LINE FROM THE BAG TO THE PATIENT ON EVERY LOAD. THERE DOES NOT SEEM TO BE ANY SAFE GUARD AGAINST THIS HUMAN FACTOR IN THE DESIGN OF THE PUMP. HOWEVER, THE PUMP DOES ALARM WITH AN "OCCLUSION" IF IT IS STARTED WITH MISLOADED TUBING, BUT THERE IS NOTHING TO PREVENT THE TUBING MISLOAD FROM HAPPENING IN THE FIRST PLACE.
BAXTER HEALTHCARE CORPORATION	COLLEAGUE 3CX	N|A	THE TRIPLE CHANNEL PUMP FAILED SUDDENLY WHILE IV INFUSIONS OF EPINEPHRINE, LEVOPHED, AND DIPRIVAN WERE INFUSING. THE PATIENT'S SBP (SYSTOLIC BLOOD PRESSURE) DROPPED TO THE 40S. THE NURSE PUSHED EPINEPHRINE FROM THE DRIP BAG THROUGH THE CVP (CENTRAL VENOUS PRESSURE) LINE PORT MANUALLY WHILE MONITORING THE ARTERIAL LINE BP (BLOOD PRESSURE) TO RISE ABOVE 90 SYSTOLIC.
CARE FUSION, INC.	ALARIS SYSTEM PC UNIT	8015	ALARIS PUMP STARTED ALARMING. THE BRAIN WAS FLASHING "MALFUNCTION" IN RED AND AFFECTED ETCO2 MODULE. BIOMED EVALUATED THE ERROR LOG OF THE PC UNIT. THE ERROR LOG INDICATED A 511.2000 COMMUNICATION FAIL ERROR. IT IS BEING RETURNED TO THE MANUFACTURER FOR FURTHER ASSESSMENT.
CARE FUSION,	SIGNATURE	7230	PUMP ALARM READ "PUMP

INC.	EDITION		MALFUNCTION.
BAXTER HEALTHCARE CORPORATION	COLLEAGUE 3CX	N|A	CHAMBER B OF THE TRIPLE PUMP WAS BEING USED TO INFUSE TPN. THE TRIPLE PUMP CHAMBER B FAILED WITHOUT WARNING, CAUSING THE TPN TO STOP. NO OTHER PUMP WAS AVAILABLE FOR BACK-UP. THE NURSE THEN STOPPED THE CVP FLUIDS FROM CHAMBER A, PLACED THE TPN TUBING INTO CHAMBER A TO RUN AT TPN RATE, AND LOCATED ANOTHER PUMP TO RUN THE CVP FLUIDS.
CARE FUSION, INC.	ALARIS SYSTEM	8000, 8100	THE FIRST INCIDENT INVOLVED A NON-DELIVERY OF NEOSYNEPHRINE. THE NEOSYNEPHRINE WAS PROGRAMMED TO ADMINISTER AND THE PUMP SHOWED THAT THE INFUSION WAS IN PROGRESS, BUT IT WAS NOT INFUSING TO THE PATIENT. THE PROBLEM WAS IDENTIFIED IN THE DRIP CHAMBER OF THE IV TUBING. THE IV TUBING WAS CHANGED. THE SECOND INCIDENT INVOLVED A BAG OF NEOSYNEPHRINE INFUSING INTO THE PATIENT DESPITE THE PUMP MODULE BEING OFF. THE NURSING STAFF QUICKLY INTERVENED TO STABILIZE THE PATIENT. THE DRUG WAS BEING ADMINISTERED AS A PRIMARY INFUSION.
CARE FUSION, INC.	ALARIS SE	7130	A LOUD ALARM WAS HEARD COMING FROM A PATIENT'S ROOM. UPON ENTERING THE ROOM, THE ALARIS PUMP WAS ALARMING AND EQUIPMENT MALFUNCTION WAS NOTED ON THE SCREEN.

			THE INFUSION STOPPED. THE ALARM ON THE PUMP WOULD NOT STOP UNTIL THE PUMP WAS TURNED OFF. THE PUMP WAS REPLACED.
B. BRAUN MEDICAL, INC.	OUTLOOK 100	OUTLOOK 100	A PATIENT WAS SEDATED AND ON A VENTILATOR WHILE RECEIVING A CONTINUOUS IV INFUSION OF NOREPINEPHRINE TO STABILIZE BLOOD PRESSURE AND MEAN ARTERIAL PRESSURE (MAP). THE RN HAD BEEN IN THE PATIENT'S ROOM, ALONG WITH A DIALYSIS RN, AND THEN LEFT MOMENTARILY TO GET MORE SUPPLIES. THE DIALYSIS RN NOTICED THE B. BRAUN PUMP WAS READING AND AUDIBLY ALARMING "ERROR," SO SHE IMMEDIATELY NOTIFIED THE PATIENT'S RN. THE PATIENT'S RN ATTEMPTED TO RESOLVE THE ERROR BUT WAS UNSUCCESSFUL, SO SHE QUICKLY SET UP A NEW PUMP, WITH NEW TUBING AND RESUMED THE MEDICATION. THE RN DID STATE THE PATIENT'S MAP DID DECLINE FROM 85 DOWN TO 69 AND 70 DURING THIS PERIOD, BUT THE BLOOD PRESSURE DID NOT HAVE A SIGNIFICANT CHANGE. THE MD WAS NOTIFIED OF THE INCIDENT. THE PATIENT'S CARE WAS RESUMED AND ALL PRESSURES STABILIZED. THE PUMP WAS TAKEN OUT OF SERVICE AND SEQUESTERED FOR CLINICAL ENGINEERING EVALUATION. CLINICAL ENGINEERING (CE) REPORTS UPON RECEIVING UNIT THEY POWERED THE UNIT

			ON AND RAN A RATE ACCURACY TEST INVOLVING A PRIMARY AND SECONDARY INFUSION. THE PUMP DID NOT ERROR BUT THE ACCURACY APPEARED TO BE OFF. THEY ALSO CHECKED THE ALARM LOG AND FOUND CONTINUOUS ERROR MESSAGES (105 AND 81). ERROR 105 REFERS TO A SHUTDOWN TIME-OUT ERROR. IT IS RECOMMENDED TO RETRY SHUTTING THE UNIT DOWN AND IF THE ERROR CONTINUES THEN TO REPLACE THE MAIN PCB. ERROR 81 REFERS TO A MAIN CRC ERROR WHICH MEANS THAT THE CRC CHECK ON THE DOMAIN BUFFER HAS FAILED. THE SOLUTION FOR THIS ERROR IS TO REPLACE THE MAIN PCB BOARD. PUMP REMOVED FROM SERVICE AND SENT TO MANUFACTURER FOR REPAIRS.
CARE FUSION, INC.	ALARIS GOLD SIGNATURE	7230EX	INFUSION PUMP STOPPED WORKING AND DISPLAYED "MALFUNCTION."
CARE FUSION, INC.	ALARIS GOLD SIGNATURE	7130D	PATIENT'S PUMP WAS FOUND TO BE BUZZING AND STATING INSTRUMENT MALFUNCTION. UNPLUGGED PUMP AND REMOVED FROM PATIENT.
B. BRAUN MEDICAL, INC.	OUTLOOK 100	OUTLOOK 100	PER THE RN, THE PATIENT WAS ON A CONTINUOUS HEPARIN INFUSION. SHE ATTEMPTED TO PLACE THE IV PUMP ON "HOLD," BUT THE IV PUMP WOULD NOT GO INTO "HOLD" MODE. SHE ATTEMPTED TO TURN THE PUMP OFF, AND AGAIN SHE WAS UNABLE TO GET THE PUMP TO POWER OFF. THE RN WAS CONCERNED AS TO WHETHER THE PATIENT RECEIVED THE

			HEPARIN AT THE RATE SHE HAD PROGRAMMED AND AS PRESCRIBED AS SHE NOTED THE APTT RESULTS HAD A DECLINE OVER THE PREVIOUS SIX HOURS OF HER CARE. SHE DID DRAW ANOTHER APTT AFTER SHE CHANGED OUT THE PUMP AND RESTARTED THE DRIP. THIS APTT WAS ALSO LESS THAN THE PREVIOUS EVEN THOUGH THE PUMP WAS NOW INFUSING. IT IS NOT CLEAR HOWEVER IF THIS WAS BECAUSE OF THE PATIENT'S METABOLIC CONDITION AND THE RATE NEEDED TO BE INCREASED OR IF THE IV PUMP WAS NOT INFUSING CORRECTLY. THE PUMP WAS TAKEN OUT OF SERVICE IMMEDIATELY AND WAS SENT TO CLINICAL ENGINEERING FOR TESTING. CLINICAL ENGINEERING WAS ABLE TO VERIFY THE COMPLAINT. THE ALARM LOG CONFIRMED THERE HAD BEEN TWO ERRORS (PRAM FAILURE AND POWER GLITCH).
CARE FUSION, INC.	ALARIS SE PUMP	7130DR	PATIENT ON ALARIS PUMP; INFUSING. BEGAN TO BEEP WITH SYSTEM MALFUNCTION ERROR MESSAGE ON SCREEN. PUMP WAS EXCHANGED, TAGGED, AND BIOMEDICAL ENGINEERING WAS PAGED AS INSTRUCTED ON INCIDENT REPORT FOR EQUIPMENT INVOLVED. CHARGE RN NOTIFIED.
B. BRAUN MEDICAL, INC.	OUTLOOK 100	OUTLOOK 100	FACILITY BECAME AWARE OF A TREND IN "SMART PUMP" ERRORS OVER THE LAST 2-3 WEEKS. FACILITY DETERMINED

			THAT THE ERRORS WERE "USER ERRORS" IN NATURE, SPECIFICALLY IN PROGRAMMING THE B BRAUN OUTLOOK 100. IT HAS COME TO FACILITY'S ATTENTION THAT WHEN STAFF IS PROGRAMMING THIS SMART PUMP, IF ONE DOES NOT PRESS "ACCEPT" PRIOR TO START, THE "SMART PUMP" WILL REVERT TO THE LAST MEDICATION, DOSE & RATE THAT WAS PROGRAMMED AND MAY BEGIN INFUSING THE WRONG RATE & DOSE WITH NO WARNING TO THE OPERATOR OF FAULTY SET-UP / PROGRAMMING. FACILITY HAS ALSO DETERMINED THAT THERE IS NO WAY TO "COMPLETELY CLEAR" THE PRIOR SETTING ON THE IV PUMP. FACILITY HAS ALSO BECOME AWARE THAT THERE IS NO WAY TO BLOCK THE SETTING FOR "POUNDS" IN DETERMINING DOSE/WEIGHT & RATE CALCULATIONS AND THERE IS NO WAY TO DETERMINE "AT A GLANCE" WHETHER THE PUMP IS SET FOR POUNDS OR KILOGRAMS. FACILITY IS ALSO AWARE THAT THE BATTERY DOES NOT CHARGE WHILE THE PUMP IS PLUGGED IN AND IN USE.
BAXTER HEALTHCARE CORPORATION	BAXTER PUMP	4360500	PUMP HAD AN UNEXPLAINED "BOOP" WHEN MOVING TRASH CONTAINER IN FRONT OF PUMP. PUMP READING 0.00, NO FLOWS, NURSE HAND CRANKED WHILE 2ND NURSE SHUT OFF AND RESTARTED PUMP AND ADJUSTED FLOWS

			ACCORDINGLY. MAP DROPPED TO 31, AND SVO2 DROPPED TO AROUND 42. NO MEDS OR VOLUME GIVEN. VITAL SIGN RETURNED TO BASELINE ONCE FLOWS RESUMED. INCIDENT LASTED APPROX. 15-20 SECONDS. NURSES WERE UNABLE TO RECREATE INCIDENT. PUMP CONTINUED TO WORK.
BAXTER HEALTHCARE CORPORATION	*	N|A	PROGRAMMED PUMP TO INFUSE 0.47CC/HR AFTER AT LEAST 10 HOURS OF INFUSION. ONLY 0.5CC WAS MISSING FROM TOTAL VOLUME.
BAXTER HEALTHCARE CORPORATION	BAXTER	MODEL #6301	CARDIZEM DRIP STARTED AND APPROPRIATE INFUSION RATE PROGRAMMED INTO IV PUMP. APPROXIMATELY 3 HOURS LATER, STAFF FOUND CARDIZEM BAG EMPTY AND CORRECT INFUSION RATE OF 5 ML/HR STILL INDICATED ON THE IV PUMP.
B. BRAUN MEDICAL, INC.	OUTLOOK 100	OUTLOOK 100	RN REPORTS PATIENT RECEIVING NORMAL SALINE IV FLUIDS WHEN THE B.BRAUN OUTLOOK 100 PUMP READ "ERROR" CODE DURING USE. RN RESPONDED TO ALARM, ATTEMPTED TO CLEAR ERROR BUT WAS UNABLE TO DO SO. RN TROUBLESHOT PROBLEM AND STILL UNABLE TO CLEAR ERROR SO OPTED TO OBTAIN NEW PUMP. NO INJURY TO PATIENT, NO CHANGE IN PT'S STATUS. PUMP WAS SENT TO CLINICAL ENGINEERING (CE) FOR INTERROGATION AND IT WAS FOUND TO HAVE HAD AN "ERROR REGARDING A TIMEOUT EXCEEDED CODE." CE WAS ABLE TO CLEAR THIS

			CODE. ACCORDING TO CE REPORT THEY FOUND A TIMEOUT EXCEEDED CODE HAPPENED TWICE, RECOMMENDATION FROM B. BRAUN BEING TO RETRY OPERATION AND IF PROBLEM CONTINUES REPLACING OF MAIN BOARD MAY BE AN OPTION. CE CONNECTED ORIGINAL TUBING SET TO PUMP, ON FIRST RUN GOT ERROR CODE 21 (MAIN MOTOR SLIPPED ON DELIVERY). ACCORDING TO CONSULTATION WITH B.BRAUN TECHNICAL SUPPORT THIS IS A COMMON PROBLEM AND RECOMMENDATION WAS "TO RUN THE PUMP ON MAXIMUM RATE TO WARM UP THE MOTOR AND TO GET RID OF THE PROBLEM" AFTER DOING SO THE PUMP DID RUN PROPERLY.
CARE FUSION, INC.	ALARIS	8015	INFANT BORN PREMATURELY. TOTAL PARENTERAL NUTRITION (TPN) INFUSING AT 2CC/HR THROUGH ALARIS PUMP. THROUGHOUT THE EVENING GRADUAL NEED FOR INCREASED OXYGEN AS WELL AS VENTILATORY NEEDS. TWO EPISODES OF HYPERGLYCEMIA. AT 0630 THE BEDSIDE RN NOTED THAT THE ENTIRE BAG OF TPN OF 183CC WAS EMPTY.
B. BRAUN MEDICAL, INC.	OUTLOOK 100	OUTLOOK 100	RN REPORTS PUMP ALARMING "ERROR" MESSAGE. TRIED TO TROUBLE SHOOT ISSUE. UNABLE TO REMOVE ERROR MESSAGE SO REPLACED WITH A DIFFERENT PUMP WHICH WORKED APPROPRIATELY. NO INJURY TO PATIENT, NO RAPID INFUSION OF ANY FLUIDS OR

			MEDICATIONS. PUMP SENT TO BIOMED FOR EVALUATION PURPOSES. EVALUATION FOUND MAIN MOTOR HAD SLIPPED. PUMP WILL BE RETURNED TO MANUFACTURER FOR SERVICE.
B. BRAUN MEDICAL, INC.	OUTLOOK 100	N|A	RN REPORTS IV PUMP BEGAN BEEPING AND FLASHING "ERROR" WHILE ATTACHED TO PATIENT. ATTEMPTED TO TROUBLE SHOOT BY FLUSHING ETC BUT COULD NOT GET ISSUE TO CLEAR. NORMAL SALINE INFUSING. NO INJURY TO PATIENT. PUMP REMOVED FROM SERVICE AND SENT TO CLINICAL ENGINEERING FOR EVALUATION. PROBLEM CONFIRMED. RECOMMENDATION PER MANUAL TO CHARGE BATTERY. BATTERY CHARGED AND PUMP RETURNED TO SERVICE.
CARE FUSION, INC.	ALARIS INFUSION PUMP	8100	THE PUMP WAS IN INFUSION MODE, LIGHT WAS GREEN, STATING 41ML VOLUME TO BE INFUSED; HOWEVER, THE BAG OF SOLUTION AS WELL AS THE TUBING WAS DRY. THERE WAS NO FLUID INFUSING! IV WAS CONNECTED TO PATIENT. PT DENIED ANY DISCOMFORT. DISCONNECTED LINE FROM PT. REMOVED PUMP AND TUBING FROM ROOM. NOTIFIED PHYSICIAN. PLACED A DEFECTIVE DEVICE DO NOT USE TAG ON EQUIPMENT.
CARE FUSION, INC.	ALARIS	N|A	NURSE INSPECTED IV TUBING AND FOUND 1 CM AIRSPACES ALTERNATING WITH 1 CM FLUID SPACES FROM PUMP ALL THE WAY TO PATIENT. PUMP DID NOT ALARM FOR AIR IN

			TUBING. BIOMEDICAL ENGINEERING INSPECTED PUMP, UNABLE TO RE-CREATE PROBLEM. PUMP APPEARS TO BE WORKING APPROPRIATELY. PATIENT WAS NOT INJURED.
CARE FUSION, INC.	ALARIS POINT OF CARE UNIT, MODEL 8000	8000	THE NURSE WAS ENTERING A BOLUS DOSE OF VERSED IN MG/KG AND RECOGNIZED THAT THE ALARIS MODEL 8000 PUMP CONTROL UNIT CALCULATED THE TOTAL DOSE DELIVERY VALUE IN MG INCORRECTLY. PATIENT WEIGHT WAS 3.6 KG AND DOSE WAS .28 MG/KG. TOTAL DOSE SHOULD HAVE BEEN 1.01 BUT THE PUMP DISPLAYED 1.23 MG. TOTAL VOLUME APPEARED TO BE CALCULATED CORRECTLY. FURTHER INVESTIGATION SHOWED THAT THE TOTAL DOSE DISPLAY WAS INCORRECT, BUT THE ACTUAL VOLUME DELIVERED WAS CORRECT AND ACCURATE. PROBLEM DETERMINED TO BE WITH MODEL 8000 ONLY (MODEL 8015 DOES NOT EXHIBIT THE PROBLEM), WITH WEIGHT BASED DRUGS IN WHICH THE UNITS FOR CONTINUOUS DELIVERY AND THE UNITS FOR BOLUS DELIVERY ARE DIFFERENT IN THE GUARDRAIL DRUG LIBRARY DEFINITION. IN THIS CASE CONTINUOUS WAS DEFINED AS MCG/KG/MIN AND BOLUS DELIVERS WAS IN MG/KG. CAREFUSION WAS NOTIFIED AND HAS DUPLICATED THE PROBLEM.
CARE FUSION, INC.	ALARIS	N|A	PUMPED ALARMED WITH "CHANNELS A & B EITHER DISCONNECTED OR

			MALFUNCTIONED, PLEASE CONFIRM." PUSHED 'CONFIRM' BUTTON, CHECKED CHANNELS" BOTH WERE ATTACHED PROPERLY. RESTARTED PUMP, ALARMED AGAIN. CHANGED VASOACTIVE DRIP TO OTHER CHANNEL. CONTINUED TO CT AND BACK WITHOUT FURTHER INCIDENT.
HOSPIRA,INC.	HOSPIRA PLUM A PLUS INFUSION PUMP	PLUM A PLUS	CONTINUED COMPLAINTS OF BATTERY FAILURES ON AN INVENTORY OF 523 PUMPS EVEN THOUGH BATTERIES HAVE BEEN REPLACED IN AS LITLE AS ONE MONTH. THE PUMP HAS NORMAL WARNINGS AND SHUTDOWN PROCESSES WHEN BATTERY DEPLETION IS DETECTED. THERE HAS BEEN A CONTINUED DISCUSSION WITH THE COMPANY. THEIR RESPONSE HAS BEEN SLOW OR NOT AT ALL. THEY HAVE INDICATED WE ARE NOT USING THEIR BATTERIES AND NOT FULLY RECHARGING THE PUMPS BETWEEN USE AS THE REASON FOR FAILURE, HOWEVER WE HAVE 255 PUMPS IN THE SAME TYPE OF ENVIRONMENT WE ARE USING WITHOUT THE WIRELESS COMMUNICATIONS THAT HAVE NORMAL BATTERY FAILURE LIFE. (1-5 YEARS) THIS CAUSES A DELAY IN TREATMENT AND EXCESSIVE FULL TIME EMPLOYEE TIME FINDING A REPLACEMENT. WE BELIEVE THE PUMP CONTINUES TO SEND A "HEARTBEAT" TO THE NETWORK SERVER EVEN WHEN TURNED OFF WHICH CAUSES PREMATURE DEPLETION. THE

			COMPANY HAS NOT RESPONDED TO THAT STATEMENT OFFICIALLY.
BAXTER HEALTHCARE CORPORATION	COLLEAGUE GUARDIAN	EEQ0465	PRIMARY IV RUNNING AT 20CC/HR POTASSIUM VIA PICC CHLORIDE 20MEQ (50CC BAG), CONNECTED VIA PIGGYBACK AT 50CC/HR. FIFTEEN MINUTES LATER RN NOTICED THAT 75% OF BAG HAD INFUSED BUT PIGGYBACK PCA STATED THAT ONLY 10CC HAD INFUSED. INFUSION STOPPED, PUMP REMOVED. UNABLE TO VERIFY IF IT INFUSED INTO PATIENT OR BACK-UP INTO PRIMARY BAG.
BAXTER HEALTHCARE CORPORATION	*	EEQ0375	PATIENT WAS RECEIVING POTASSIUM PHOSPHORUS REPLACEMENT PER ELECTROLYTE PROTOCOL. TWO HUNDRED FIFTY CC'S OF IV PIGGYBACK HUNG AT 0930 AND PUMP SET TO RUN MED IN OVER 4 AND 10 MINUTES HOURS. MEDICATION MAY INFUSE OVER 4-6 HOURS. AT 11:30 A.M. I WAS CHECKING PUMP AND NOTED THAT BAG WAS COMPLETELY DRY BUT PUMP SHOWED THAT 148CC REMAINED TO BE INFUSED. I RECHECKED THE PROGRAM VOLUME TO BE INFUSED AND THE RATE OF INFUSION WERE STILL SET AT 250 CC'S. CARDIOLOGY AND PRIMARY TEAM NOTIFIED. PHARMACIST STATED NO ADVERSE EFFECT FROM THIS, BUT AT THE HIGHER INFUSION RATE THERE MAY BE LESS ABSORPTION OF THE MED SO THE FUNCTIONAL USE LEVEL OF PHOSPHORUS MAY NOT BE CORRECT.
CARE FUSION,	ALARIS	10011274	NURSE WAS REMOVING

INC.	PUMP		NITROGLYCERINE TUBING FROM PUMP CHANNEL AND WHEN SHE OPENED THE CHANNEL DOOR, THE AUTOMATIC TUBING CLAMP FAILED AND THE PATIENT RECEIVED A BOLUS OF NITROGLYCERINE. SYSTOLIC BLOOD PRESSURE DROPPED TO THE 50'S. NURSE MANUALLY CLAMPED THE TUBING AND DISCONNECTED IT FROM THE PATIENT. PATIENT GIVEN LEVOPHED UNTIL BLOOD PRESSURE WAS STABILIZED.
HOSPIRA,INC.	SYMBIQ IV INFUSION PUMP	1602604	PATIENT IS RECEIVING WEEKLY CHEMOTHERAPY AND PREMEDICATION TREATMENT FOR DIAGNOSED VULVAR CANCER. PATIENT GIVEN PRE-MEDICATION CONSISTING OF ZOFRAN AND DECADRON IV ON TOTAL VOLUME PER PHARMACY OF 79 MLS TO INFUSE OVER 15 MINUTES AT 316 ML/HR. SYMBIQ PUMP PROGRAMMED ACCORDINGLY TO PHARMACY PARAMETERS ON PREMEDICATION BAG. AT APPROXIMATELY 1040 RN TALKED WITH PATIENT, NOTING THAT MEDICATION WAS DELIVERED DOWN TO AIR IN BAG AND CHAMBER AND THE PUMP WAS STILL PUMPING THE AIR CLOSER TO PATIENT, NOT YET HAVING DETECTED IT AND PUMP DID NOT GIVE "AIR IN LINE" ALARM. RN CLOSED WHITE ROLLER CLAMP TO STOP MEDICATION/AIR IN TUBING WHERE IT WAS AT. PUMP WAS ALERTING OCCLUSION (D/T ROLLER CLAMP ACTIVATED). PUMP READING VOLUME TO BE INFUSED WAS STILL AT 4.08

			MLS. PUMP TURNED OFF AFTER TUBING REMOVED. TUBING SAVED AND MARKED AT 54 INCHES PAST CHAMBER THAT LOADS INTO HOSPIRA SYMBIQ, FULL OF AIR. PUMP AND TUBING WERE SENT TO BIOMEDICAL DEPARTMENT AND HAVE BEEN SEQUESTERED. BIO-TECHNICIAN HAS BEEN UNABLE TO DUPLICATE THE "AIR IN LINE" PROBLEM. PATIENT RECEIVED INFUSION OF CISPLATIN 80 MG VIA ANOTHER SYMBIQ PUMP WITH 500 ML DEXTROSE 5% 1/2 NORMAL SALINE WITH 10 MEQKCL, 1 GM MAGNESIUM SULFATE & 25 GM MANNITOL INFUSED OVER 60 MINUTES. NO COMPLICATIONS OR ADVERSE EFFECTS FROM THE INFUSION. NO AIR REACHED THE PATIENT.
HOSPIRA,INC.	SYMBIQ	1602604 SINGLE	PATIENT WITH HYPOGAMMAGLOBULEMIA WAS RECEIVING A SERIES OF INTRAVENOUS IMMUNE GLOBULIN FLEBOGAMMA INFUSIONS MONTHLY. PATIENT RECEIVED 25 MG BENADRYL IV. RN PUT 0.5 ML BENADRYL IN 50 ML NORMAL SALINE IV BAG. PUMP SETTING FOR BENADRYL WAS FROM DRUG LIBRARY 50 ML VOLUME TO BE INFUSED FOR 15 MINUTES. AT CONCLUSION OF 15 MINUTES, RN WAS IN ANOTHER ROOM WHEN SHE HEARD IV PUMP WITH SOFT ALARM. ON ARRIVAL IN THE PATIENT'S ROOM, THE IV PUMP WAS STILL SOFT ALARMING, PUMP HAD CHANGED TO KEEP VEIN OPEN 20 ML SETTING AND TOTAL VOLUME IN WAS 51.2 ML. RN

			NOTICED THAT THERE WAS AIR IN LINE PAST THE CASSETTE. SHE MEASURED 34 INCHES OF AIR FROM THE CASSETTE DOWN THE TUBING TOWARD THE PATIENT. PUMP WAS PUT ON STANDBY SETTING, BIOTECHNICIAN WAS NOTIFIED, AND PUMP AND IV TUBING WAS GIVEN TO BIOTECHNICIAN. NO AIR REACHED THE PATIENT. HOSPIRA WAS NOTIFIED.
SMITHS MEDICAL MD, INC.	CADD	PRIZM VIP	PATIENT INDICATED THAT THE PUMP WAS STARTED DURING THE EVENING AND DISCOVERED THE NEXT MORNING THAT TOTAL PARENTERAL NUTRITION (TPN) HADN'T BEEN DELIVERED OVERNIGHT. SHOP TESTS OF THE PUMP REVEALED NO DEFECTS. THE PUMP WAS FOUND TO STILL BE CONFIGURED WITH THE FLOW SETTINGS INTENDED FOR THE PATIENT THAT DIDN'T RECEIVE THE TPN. TESTS WERE PERFORMED WITH THESE SAME SETTINGS AND OPERATION WAS FOUND TO BE WITHIN THE MANUFACTURER'S SPECIFICATIONS. HOME CARE PHARMACY WAS NOT AWARE OF ANY EXTENUATING CIRCUMSTANCES THAT MAY HAVE EXISTED THAT WOULD EXPLAIN WHY TWO PUMPS MIGHT HAVE BEEN REPORTED TO FAIL ON THE SAME PATIENT WITH NO PROBLEMS DETECTED WITH EITHER PUMP SUBSEQUENTLY. GIVEN THE CIRCUMSTANCES THE MOST LIKELY

			EXPLANATION WAS THAT THE PATIENT HAD FORGOTTEN INSTRUCTIONS ON HOW TO OPERATE THE PUMP AFTER INITIALLY SUCCESSFULLY UTILIZING THE PUMP. WHILE POSSIBLE, THE PROBABILITY THAT AN INTERFERING SOURCE WITHIN THE HOME PRODUCED THE PROBLEMS SEEMS LOWER.
HOSPIRA,INC.	SYMBIQ	1602604 SINGLE	PATIENT WITH CHRONIC NON-HEALING WOUND OF LOWER EXTREMITY AND WITH A RECENT FLAP PLACEMENT HAD AN INFUSION OF VANCOMYCIN 750 MG IV IN 250 ML NORMAL SALINE BAG. THIS SETTING WAS SELECTED FROM THE IV PUMP LIBRARY TO RUN FOR 1 HOUR. AT END OF INFUSION, PUMP HAD SOFT ALARM OF RATE 0/VOLUME TO BE INFUSED 0. THERE WAS STILL MEDICINE FLUID IN THE BAG; THE RN ESTIMATED 25 ML REMAINING, ADDED VOLUME TO BE INFUSED 25 ML AND RESTARTED PUMP. AFTER INFUSION, PUMP SOFT ALARMED RATE 0/VOLUME TO BE INFUSED 0, AND PUMP AUTOMATICALLY STOPPED. RN RESPONDED TO ALARM. PUMP HAD ONLY BEEPED TWICE. RN VISUALIZED THAT IV BAG WAS EMPTY, DRIP CHAMBER WAS EMPTY, AND AIR IN LINE PAST THE CASSETTE CHAMBER. IV TUBING WAS REMOVED FROM PUMP. MEASURED AMOUNT OF AIR IN LINE FROM CASSETTE TO FLUID WAS 42 INCHES. FROM LINE WHERE FLUID STARTED TO END OF TUBING (PATIENT SIDE) WAS 35.5 INCHES. NO AIR REACHED THE PATIENT. PUMP

			WAS PUT ON STANDBY AND PUMP REMOVED FROM SERVICE. BIOTECHNICIAN WAS NOTIFIED; PUMP AND TUBING WERE GIVEN TO BIOTECHNICIAN.
HOSPIRA,INC.	SYMBIQ	1602604 SINGLE	ONCOLOGY RN PROGRAMMED THE HOSPIRA SYMBIQ PUMP TO DELIVER CHEMOTHERAPY INFUSION OF CISPLATIN AND GEMCITABINE FOR RECURRENT BLADDER CANCER. WHEN RN RETURNED TO PATIENT'S ROOM TO INVESTIGATE AN ALARM, SHE FOUND THE PUMP WAS ALARMING "AIR IN LINE." RN NOTED THAT THE AIR WAS WELL BEYOND THE PUMP AND WAS INCHES FROM THE PATIENT'S PERIPHERAL IV SITE. RN STOPPED THE PUMP AND TOOK IT OUT OF SERVICE. NO AIR REACHED THE PATIENT. BIOTECH WAS NOTIFIED; PUMP RETURNED TO HOSPIRA FOR EVALUATION.
HOSPIRA,INC.	SYMBIQ	1602704 DOUBLE CHAMBER	PATIENT WITH DIAGNOSIS OF ANEMIA IN PREGNANCY WAS RECEIVING VENOFER INFUSIONS. PHYSICIAN ORDER WAS WRITTEN FOR 200 MG VENOFER OVER 30 MINUTES. RATE WAS 200 ML/HR; DOSE RATE 400. AT END OF INFUSION, IV PUMP ALARMED "AIR IN LINE", GAVE AN AUDIBLE ALARM AND FLASHED RED. RN OBSERVED 46 INCHES OF AIR PAST THE CASSETTE. RN SHUT OFF IV, DISCONNECTED IV FROM PATIENT. NO AIR REACHED THE PATIENT. PATIENT WAS NOT HARMED. PUMP WAS TAKEN OUT OF SERVICE AND BIOTECH

			NOTIFIED TO SEQUESTER PUMP. HOSPIRA WAS NOTIFIED AND (B) (4) FILED AN FDA REPORT FOR HOSPIRA.
HOSPIRA,INC.	SYMBIQ	1602604 SINGLE	PATIENT WITH IRON DEFICIENCY ANEMIA WAS RECEIVING IV INFUSION OF VENOFER 200 ML/HR VOLUME TO BE INFUSED 120 ML. PROGRAM SELECTION WAS IV FLUID AND MEDICATION WAS VENOFER. WHEN THE INFUSION WAS COMPLETED AT 10:45 AM, THE PUMP KEPT PUMPING AIR PAST THE PUMP FOR APPROXIMATELY 46 INCHES. AIR DID NOT REACH THE PATIENT. THE PATIENT WAS NOT HARMED. THE ONLY ALARM GIVEN WAS "END OF INFUSION ALARM." NURSE SHUT OFF PUMP AND CALLED BIOTECHNICIAN. PUMP WAS TAKEN OUT OF SERVICE. PUMP AND TUBING SENT TO HOSPIRA FOR INVESTIGATION.
SMITHS MEDICAL MD, INC.	CADD SOLIS	2100	OVER THE PAST FEW MONTHS, I'VE BEGUN TO SEE AN INCREASE IN THE NUMBER OF DOWNSTREAM OCCLUSION ALARMS. CLINICAL ENGINEERING HAS DOCUMENTED SEVERAL INSTANCES IN WHICH THE OCCLUSION ALARM IS OCCURRING AT 4-5 PSI WHEN THE INITIAL TEST VALUE WHEN PURCHASED 14 MONTHS AGO WAS NEAR 18 PSI.
BAXTER HEALTHCARE CORPORATION	SIGMA SPECTRUM	SPECTRUM	AT 1300, CONFIRMED SIGMA SPECTRUM PUMPS INFUSING TPN AND LIPIDS. AT 1400, RIGHT ARM SWOLLEN AND IV INFILTRATION. PUMPS REMOVED.

CARE FUSION, INC.	ALARIS PCU (MODEL 8000), ALARIS PUMP (MODEL 8100)	8000/8100	ERRORS WITH ALARIS PCU (MODEL 8000) & ALARIS PUMP (MODEL 8100). READINGS CHANGED BY UNIT, ALTHOUGH STAFF ENTERED CORRECTLY.
SIGMA INTL.	SPECTRUM	N|A	UMBILICAL ARTERY CATHETER FLUIDS INFUSING AT 0.5CC/HOUR. WHEN RESET VOLUME TO BE INFUSED, THE PUMP ALARMED. ABOUT ONE HOUR LATER, THE PUMP WAS OFF. THE CHARGE COMPLETE SCREEN WAS DISPLAYED. PUMP TURNED BACK ON AND RESUMED FLUID INFUSION.

Additional Information:

[1] – What Is an Infusion Pump? (2010). http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202495.htm[43]

[2] – Infusion Pump Improvement Initiative (2010). Retrieved from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202501.htm[44]